BIOSECURITY AND BIOSAFETY SYSTEMS IN THE PHILIPPINES AND NEW ZEALAND: A CROSS-CASE ANALYSIS

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ABSTRACT

There is a growing importance for both biosecurity and biosafety globally and locally. In this context, this study examined and compared the biosecurity and biosafety systems of the Philippines and New Zealand. This study also considered the central issue of whether the international idea that biosecurity should be the strategic and integrated approach covering and encompassing biosafety and other related instruments, is present or being practised in the national context. This study utilised a qualitative research framework. It followed a case study approach as a process and a product of analysis, and employed triangulation technique of in-depth interviews, observation and used of pertinent/documents in gathering the relevant data and information. This study found that there are complexity of systems, policies, legislation, regulations, and cross-cutting issues that surround biosecurity and biosafety in the Philippines and New Zealand. In terms of biosecurity encompassing biosafety in the local context, this study revealed that such a concept is not yet present in the Philippines, whilst, to some extent it is happening in New Zealand. This study concluded that unless steps are taken to make national policies better informed, enhance understanding of the nature and relevance of biosecurity, and set strategic and operational priorities, then there will be a continuing overlap between biosecurity and biosafety at the national or local level.

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ACRONYMS

AFMA	Agriculture and Fisheries Modernisation Act
AO	Administrative Order
ASEAN	Association of Southeast Asian Nations
BAFPS	Bureau of Agriculture and Fisheries Standards
BAI	Bureau of Animal Industry
BFAD	Bureau of Food and Drug
BFAR	Bureau of Fisheries and Aquatic Resources
BMAC	Biosecurity Ministerial Advisory Committee
BNZ	Biosecurity New Zealand
BPI	Bureau of Plant Industry
BSE	Bovine Spongiform Encephalopathy
BSU	Biosecurity Strategy Unit
CBD	Convention on Biological Diversity
COAG	Committee on Agriculture
COP/MOP	Conference of the Parties/Meeting of the Parties
DA	Department of Agriculture
DENR	Department of Environment and Natural Resources
DOH	Department of Health
DOST	Department of Science and Technology
EO	Executive Order
ERMA	Environmental Risk Management Authority
FAO	Food and Agriculture Organisation of the United Nations
FFS	Farmer Field School
FMD	Foot-and-Mouth Disease
GDP	Gross Domestic Product
GEF	Global Environment Facility

GIA	Grants in Aid
GMO	Genetically Modified Organism
HSNO	Hazardous Substances and New Organisms
IAG	Interim Assessment Group
IAS	Invasive Alien Species
IBC/IBSC	Institutional Biosafety Committee
IPM	Integrated Pest Management
IRMF	Integrated Risk Management Framework
IRRI	International Rice Research Institute
ISPM	International Standards for Phytosanitary Measures
LMO	Living Modified Organism
MAF	Ministry of Agriculture and Forestry
MFish	Ministry of Fisheries
MOU	Memorandum of Understanding
NBF	National Biosafety Framework
NCBP	National Committee on Biosafety of the Philippines
NCC	National Coordinating Committee
NCSO	National Census and Statistics Office
PAWB	Protected Area and Wildlife Bureau
PA	Protected Area
PBG	Philippine Biosafety Guidelines
PCE	Parliamentary Commissioner for the Environment
PCSD	Philippine Council for Sustainable Development
PD	Presidential Decree
PHES	Potentially Harmful Exotic Species
RA	Republic Act
RCGM	Royal Commission on Genetic Modification
SARS	Severe Acute Respiratory Syndrome

SCBD	Secretariat of the Convention on Biological Diversity
SPS	Sanitary and Phytosanitary Measures
UNEP	United Nations Environment Programme
UPLB	University of the Philippines Los Baños
WTO	World Trade Organisation

GLOSSARY OF FILIPINO AND MĀORI TERMS

Filipino:

Kaingin	shifting cultivation; slash and burn farming
Kasakalikasan	literally means for nature; used to represent the program Farmer Field School (FFS), a component of Integrated Pest Management (IPM)

Māori:

iwi	people, nation; modern usage - tribe; (also bones)
taonga	treasured possessions or cultural items, anything precious
Waahi tapu	ancestral lands, sacred places

CHAPTER 1

INTRODUCTION

Today's reality meant that the agriculture and health and food safety institutions needed an expanded international vision and a broader mandate; and needed to be restructured to include stronger alliances between, and integration of the activities of various sectors (FAO 2003).

The extent of international trade and travel has made an unprecedented leap in the 21st century. Globalisation and changes in transport technologies have resulted in greater and more rapid trade as well as the development of new trade routes (Sutton 2003). These phenomena have huge economic, social, cultural and environmental implications.

Pests, diseases and potentially harmful organisms can threaten the biodiversity, ecosystems, public health and economy of developed and developing nations. The potential pathways for spreading such pests and diseases are: accelerating movement of people by air from continent to continent; transboundary movement of cargos and containers; and large increases in the volume of food and agricultural products being traded internationally. Improved biosecurity is being sought among national bodies responsible for enforcing sanitary, phytosanitary and zoosanitary measures to better protect human, animal and plant life and health without creating unnecessary technical barriers to trade (FAO 2003). In recent years, there has been greater recognition of the importance of biosecurity in relation to the protection of the economy, human health and the environment. Biosecurity policies have been gradually evolving from a narrow focus on production pests to a broader awareness of multiple economic, social and ecological objectives (Jay *et al.* 2003).

Just as rapid as the increase in the globalisation of trade and travel is the pace of technological change in biotechnology. Modern biotechnology, through genetic engineering in particular, has revolutionised the agricultural and health sectors. These sectors have witnessed an exponential growth in the use of biotechnology over the last three decades, especially in advanced industrialised countries (Gupta 2001). A growing array of products derived from the use of modern biotechnology is being transferred across the globe giving rise to the issue and concept of biosafety. Biosafety as defined by the Secretariat of the Convention on Biological Diversity (2000) refers to the need to protect the environment and human health from possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognised as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care (SCBD 2000).

These recent developments highlight the growing importance of both biosecurity and biosafety. Biosecurity is a relatively new concept and a term that is evolving as usage varies among countries with different specialist groups using it in different ways. The issues encompassed in biosecurity have traditionally been dealt with in a sectoral manner by means of food safety laws, animal and plant quarantine and pesticide regulations (FAO 2003). Emerging issues of biosafety and the necessity to control the introduction and management of invasive alien species into the environment mean that a growing number of concerns need to be addressed.

The Food and Agriculture Organisation of the United Nations (2003) defines biosecurity as a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risks. Biosecurity covers the introduction of plant pests, animal pests and diseases, and zoonoses; the introduction and release of genetically modified organisms (GMOs) and their products; and the introduction and management of invasive alien species and genotypes. The FAO regards biosecurity as "a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity" (FAO 2003: 1).

As the FAO tends to encompass the issues of GMOs within the context of biosecurity, another relevant instrument, the Cartagena Protocol on Biosafety (the Protocol) to the Convention on Biological Diversity (CBD), came into force on 11 September 2003. Its purpose is to regulate the safe use, handling, transit, and transboundary movement of living modified organisms (LMOs)[1]. The Protocol in effect reflects a sectoral approach to regulation in this area.

The current situation indicates that there could be potential overlaps and perhaps areas of potential conflict between the two systems. The need for a coordinated and/or unified approach to handling the issues of biosecurity and biosafety cannot be underestimated. Furthermore, the coming into force of the Cartagena Protocol as a binding international legal instrument has direct relevance to biosecurity from the point of view of potential impacts and implications of LMOs on biological diversity and the environment. This calls for the strengthening of the national and regional governments and institutions in their systems in the light of international and regional harmonisation. In view of this, it is imperative to look into the systems and frameworks both in "developed" and "developing" countries, which encompass policy, regulation, capacity and implementation.

It is in this context, that this thesis examines and compares the biosecurity and biosafety systems of the Philippines and New Zealand. This study builds up from the experiences and lessons learned from

[1] The terminology used for such organisms is a subject of debate.

both countries to make a cross-systems/cross-case analysis. Whilst New Zealand leads the Philippines in terms of the implementation and management of an advanced biosecurity system, it is notable that the Philippines has been grappling with the issue of effective management of genetically modified organisms (biosafety) particularly in agriculture and social development, for a greater period than New Zealand. This contrast, in part, reflects the differing philosophies of the two countries and regions in terms of agriculture, development, and conservation. It is also an important distinction in terms of policy approach and policy outcomes.

Moreover, this thesis considers the central issue of whether the international idea that "biosecurity should be the strategic and integrated approach covering and encompassing biosafety and other related instruments" (FAO 2003: 1); is present or being practised in the national context. During the commencement of this study, the Cartagena Protocol on Biosafety came into force in September 2003; New Zealand released its first Biosecurity Strategy in August 2003; and the Philippines was developing its National Biosafety Framework. Hence, this thesis shows the timeliness of this research and the opportunities that arise in view of effecting change in these areas.

1.1 Research Questions

The study focuses on addressing the following questions:

1. What are the contrasting biosecurity and biosafety policy approaches in the Philippines and New Zealand?
2. Why and how effective are the differing frameworks and strategies being used in both countries for biosecurity and biosafety?
3. What are the gaps and/or potential overlaps within and between the biosecurity and biosafety systems?
4. What are the challenges and cross-cutting issues in view of biosecurity and biosafety governance?
5. What are the shared norms in biosecurity and biosafety in both countries?
6. How does the idea of biosecurity encompassing biosafety operate in the national or local context, *i.e.* in the case of the Philippines and New Zealand?

1.2 Significance of the Study

This thesis contributes to a better understanding of the way biosecurity and biosafety systems work in the case of a developed country like New Zealand and a developing country such as the Philippines. For the Philippines, it leads to a greater understanding of how the country may successfully integrate a biosecurity system alongside their current biosafety system. Also, there is a value from this study for

New Zealand. The Philippines and New Zealand have similar strategic interests in terms of their presence and interest in the Pacific and South-East Asia; as an example both countries contributed to peacekeeping efforts in East Timor. This study could lead to increased dialogue and understanding of both countries' approaches to biosecurity and biosafety; and learn from their unique 'lessons-learned' and experiences.

This thesis also contributes to knowledge of the way in which the global idea of biosecurity encompassing biosafety works within the national or local context. The findings and discussion in this thesis will interest: policy advisors; academics and researchers working in the areas of biosecurity and or biosafety; government officials and planners; and social and environmental scientists, among others. This study also opens up areas for further and potential research in the relatively new field of biosecurity and biosafety.

1.3 Structure of the Study

The structure of this study is ordered in such a way that while the chapters can stand alone its chronological order facilitates a better understanding of the whole thesis.

Chapter 2 reviews past research undertaken on the topic in the Philippines and New Zealand, as well as overseas studies, noting the gaps in the body of research.

Chapter 3 outlines the research methodology used in the study. In particular, it describes the research locale, the research paradigm the research design/approach, data gathering techniques, data analysis and the researcher's bias. The primary methodology used was the integrated element of the qualitative research approach to case-studies on the way biosecurity and biosafety is practised in two countries. The researcher employed the triangulation technique of in-depth interviews, secondary/archived documents, and observation in informing the case-study analysis.

Chapter 4 profiles and outlines the enabling policies, laws, regulations and regulatory regime for biosecurity and biosafety in the Philippines.

Chapter 5 profiles and outlines the enabling policies, laws, regulations and regulatory regime for biosecurity and biosafety in New Zealand

Chapter 6 presents and discusses the intertwining issues, concerns and challenges to biosecurity and biosafety in the Philippines.

Chapter 7 presents and discusses the crosscutting issues, concerns and challenges to biosecurity and biosafety in New Zealand.

Chapter 8 provides a cross-case analysis from the two case studies of the experiences of the Philippines and New Zealand, in view of their biosecurity and biosafety systems.

Chapter 9 presents a summary of the study by outlining in bullet points the synthesized concepts/lessons from the field as an outcome of the study. It also presents the conclusion of the study, the implications of the findings, the recommendations for future research and the limitations of the study.

CHAPTER 2

REVIEW OF LITERATURE

An understanding of any research topic requires one to go back to previous research as sources for learning. This study of biosecurity and biosafety systems in the Philippines and New Zealand is no exception. This Chapter reviews the previous researches and documents relevant to the fields of study.

2.1 Biosecurity in the International Context

"Biosecurity is of growing interest as a result of major international developments, including globalisation of the world economy, the rapid increase in communications, transport and trade, technological progress, and increased awareness of biological diversity and environmental issues" (FAO 2001: 2). During the Sixteenth Session of the Committee on Agriculture (COAG) of the Food and Agriculture Organisation of the United Nations (FAO) in March 2001, the Committee agreed to endorse a common integrated approach to biosecurity. The COAG identified that biosecurity is a key requirement for achieving the goals set out in the FAO Strategic Framework by promoting, developing, and re-enforcing policy and regulatory frameworks for food, agriculture, fisheries and forestry. It was noted that biosecurity has direct relevance to food safety, the conservation of the environment (including biodiversity), and sustainability of agriculture. This led to a an Inter-agency Meeting and an International Expert Consultation in September 2002 to improve understanding of the nature and relevance of biosecurity in food and agriculture in view of advancing its practical implementation particularly in developing countries (FAO 2002). In 2003, a technical consultation on biological risk management in food and agriculture was conducted in Thailand. The consultation recommended that "countries should determine the potential for synergies and harmonisation within their national and sub-regional regulatory frameworks that would result from a holistic and coordinated approach to biosecurity. Policy makers should recognise the importance of biosecurity as a key element of sustainable development, and the benefits, including in trade that can be gained from comprehensive approaches to biosecurity" (FAO 2003: 8).

In the United States for instance, Meyerson & Reaser (2002) illustrated and emphasized the need for the United States and other governments to adopt a comprehensive approach to biosecurity, so as to minimise the risk or harm caused by (non-native) organisms to the economy, environment and human health. They have identified that although there were numerous reports and papers recommending actions to prevent the movement and establishment of harmful organisms in the United States, these

materials focused only on individual sectors (*i.e.* health, agriculture, and environment) but without a vision for building a comprehensive, integrated biosecurity system.

The need for strengthening biosecurity for food security and agricultural trade was also identified in the Asia-Pacific Region. In an FAO (2004) report on 'Regional Strategic Framework for Asia and the Pacific towards a Food-Secure Asia and Pacific', strengthening biosecurity in the region was one of the six priority programme areas. The report highlighted the fact that production systems in Asia and the Pacific are rapidly evolving in response to increasing demand for food and agricultural products as well as to globalisation pressures. Furthermore, the report underscored that "biosecurity is now one of the urgent issues that confronts both the region and the international community" (FAO 2004: 19). The report also identified that more coordinated efforts are required to take into account overlapping global and regional issues encompassing sustainable agriculture, food security, environmental protection, loss of biodiversity and trade. The need for the development of national policies and regulatory frameworks relating to biosecurity and biosafety was identified as a major step on this front. However, the interrelated biosecurity issues in Asia and the Pacific remain inadequately understood or addressed (FAO 2004), and the studies related to such issues are scarce if not nil.

2.1.1 Biosecurity and Biosafety: peculiarities in usage and definition

Biosecurity and biosafety are relatively new concepts. These are terms that are evolving as usage varies among countries with different specialist groups using them in different ways (FAO 2003). FAO uses the term biosecurity in relation to sanitary, phytosanitary and zoosanitary measures applied to food and agricultural systems. They also use the term synonymously with "*Biosecurity* in food and agriculture". In a series of consultations conducted by the FAO from 2001 to 2003, the need for translation and harmonisation of terminology has been emphasized. They found that the usage of the term biosecurity varies among countries. For instance they noted the variation in translation particularly for Spanish and French. The terms "Bioseguridad" (Spanish) and "Biosécurité" (French) have been used in the Cartagena Protocol on Biosafety for the translation of the word biosafety. As a result, the FAO COAG recommended standardising the use of the English term "*Biosecurity*" (*i.e.* capitalised, italicised and not translated at all) in all languages for the purpose of their consultations and reporting. Tucker (2003) noted further that although the terms biosecurity and biosafety were often used interchangeably, they refer to different issues.

There are notable differences (within and between terms) in the definitions of biosecurity and biosafety. For instance, according to Meyerson & Reaser (2002) the term biosecurity was previously used in the United States primarily to describe an approach designed to prevent or decrease the transmission of infectious diseases in crops and livestock. They observed however, that the term has

been applied more broadly in recent times to encompass efforts to prevent harm from both intentional and unintentional introductions of organisms to human health, infrastructure, agriculture and the environment. Tucker (2003) however, provided a contrasting definition of biosecurity as a term to denote policies and procedures designed to prevent the deliberate theft, diversion, or malicious use of high-consequence pathogens and toxins. In New Zealand, the definition of biosecurity also evolved through time. The New Zealand Biosecurity Act 1993 does not specifically define the term 'biosecurity' however, the title of the Act does contain the following purpose "...the exclusion, eradication, and effective management of pests and unwanted organisms." Subsequently, in 2003 the New Zealand Biosecurity Strategy provided an expanded definition of biosecurity to mean the exclusion, eradication or effective management of risks posed by pests and diseases to the economy, environment and human health.

Finally, the FAO COAG in 2003 provided a holistic definition of biosecurity. It states that "biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk." It emphasises that biosecurity should "cover(s) the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotypes." The FAO looks at biosecurity as a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity.

2.2 Biosecurity in the Philippines

In the Philippines biosecurity is a relatively new term. There is no specific document or official publication that has particularly studied biosecurity systems in the country, according to the FAO or New Zealand's definition of biosecurity. However, Padolina[2] (2004) directly linked the issue of biosecurity and its relevance to food security and highlighted the imperatives for a biosecurity system in the country. Responsibilities for biosecurity issues in the country is dispersed among different sectors involving agriculture, health, the environment, forestry, fisheries, trade and industry (FAO 2004).

[2] Dr. William Padolina, Deputy Director General for Partnership of the International Rice Research Institute (IRRI), presented a topic on: Biosecurity and Food Security at SEARCA on 29 January 2004. A PowerPoint presentation for the said topic was obtained by the researcher.

In view of the limited study on the topic of biosecurity in the country, this section focuses on reviewing the literature that revealed the extent of a problem directly related to biosecurity in the Philippines. It centres on the growing problem of invasive alien species in the country and highlights the pressing need for a system that will address and manage the risks associated with them.

2.2.1 The Case of Invasive Alien Species

In the Philippines, the numbers of introduced alien species are growing. Most of these species, especially the tree species, are introduced for economic reasons and for forest rehabilitation purposes. Almost all ecosystems are affected. The more invasive alien species are the tilapia (*Tilapia mossambica*), Thai catfish (*Clarias batrachus*), golden apple snail (*Pomacea canaliculata*), water hyacinth (*Eichhornia crassipes*), *Chromolaena odorata*, *Lantana camara* and the insect pests associated with introduced tree species (Uriarte 2005).

Halos (2003) reported there are already known instances of new introductions that have not resulted in economic benefit but rather have had adverse environmental and economic consequences in the Philippines. One particular species, the water hyacinth (*Eichornia crassipes* Mart Solms), originally from tropical America and introduced as ornamental in 1912[3] has become a noxious weed, clogging waterways, covering swampy areas, and crowding out other species in the area. A look out of the airplane window as one approaches Manila Airport will show the number of water inlets following to the Pasig River which are clogged and rendered impassable by water hyacinth.

In the report of Halos (2003), the introduction of some aquatic species resulted in biodiversity and economic losses. For instance, the Thai catfish (*Clarias batrachus*) introduced in 1972 displaced the native catfish (*Clarias macrocephalus*) in its native habitat. More recently, an aquarium catfish species, the janitor fish (*Plecostomus hypostomus*), introduced in the 1990s is becoming a problem for fishermen in Laguna Lake. They claimed that this fish can destroy fish nets and compete for food with the more valuable commercial fish species[4].

One of the worst introductions is the golden kuhol. This snail, a native of South America, was introduced through Taiwan between 1982 and 1984 by a private individual, but the government soon picked it up as a livelihood project. Raising golden kuhol was primarily intended for food consumption in view of its nutritional benefits and as alternative source of income for small-scale farmers (Halos 2003). By 1986, this pest was reported to have damaged 300 hectares of rice fields in Cagayan Valley (Guerrero 2001). Golden kuhol continues to infest 11% of the irrigated rice fields and

[3] PROSEA, Plant Resources of Southeast Asia Vol. 11
[4] Philippine Daily Inquirer, Aug 8, 2003

appears to have displaced the native snail, *Pila luzonica*. Farmers spent an estimated US$23 million between 1980 and 1998 in an effort to control this pest (Halos 2003, Uriarte 2005).

Of the introduced tree species, ipil-ipil (*Leucena leucocephala*) and kakawate (*Gliricidia sepium*) can be seen to have spread around the country. These species behave like pioneer species and their impacts into the ecosystem have not been recorded yet. However, the introduction of the giant ipil-ipil has facilitated the infestation of a new insect pest, (*Psyllid* sp) and this has checked the rapid spread of the giant ipil-ipil. Early in its introduction, ecologists warned that this type of ipil-ipil could develop into a weed because it was claimed to be more pest resistant than the existing dwarf types. (Halos 2003, Uriarte 2005). The list of alien species in the country and their effects on the ecosystems is presented in the table below.

Table 1. Effects on the Ecosystems of some Alien Species Introduced in the Philippines[5].

Alien Species	Effects to the Ecosystem
I. Wetland Ecosystems	
A. Fish	
1. Thai catfish (*Clarias batrachus*)	The introduction in Luzon led to the displacement of native catfish (*Clarias macrocephalus*), which became widespread in many parts of the country It was thought they would boost the aquaculture industry, however they were not commercialized because of their tough flesh
2. African catfish (*Clarias gariepinus*)	Not yet considered invasive but on the "watched list"
3. Tilapia (*Tilapia mossambica*)	Has invaded most lakes and river and now even inhabits saline estuaries
4. Janitor fish (*Hypostomus plecostomus*)	For aquariums; invaded Laguna Lake; Not yet considered invasive but on the "watched list"
B. Snails	
1. African giant snail (*Achatina fulica*) and 2. Golden apple snail (*Pomacea canaliculata*)	Purposely imported to avert malnutrition as source of protein and as an aquarium novelty; dominated many ecosystems thus causing huge losses; led to the displacement of the native snail (*Pila luzonica*); major pest to the newly planted rice seedlings
C. Aquatic Plants	
1. Water fern (*Salvinia molesta*)	Rapidly invading other bodies of water; a problem weed in Iloilo especially in irrigated rice field; clogs waterways

[5] This table is adapted from Uriarte 2005.

Table 1. ...*cont'd.*

Alien Species	Effects to the Ecosystem
2. Water hyacinth (*Eichhorni crassipes*)	Rapidly invading Marikina and Laguna rivers; reduces growth of plankton that provides food for fish; clogs waterways
D. Amphibians	
1. Marine toad (*Bufo marinus*)	A very prolific toad species; caused the decrease in the population of native frogs in Negros
2. American bullfrog (*Rana catesbeina*)	Displaced native frogs
II. Forest Ecosystems	
A. Tree Species and Insect Pests	
1. *Gmelina arborea*	Host of *Ozola minor*, *Attacus* and *Xyleutis species*; infested several *Gmelina arborea* stand in the country and could be a widespread problem in the future
2. *Acacia mangium*	Host of *Anoplophora luciphor*; infested *Acacia mangium* and could potentially infest other commercially introduced *Acacia* sp. in the country.
3. *Eucalyptus camaldulensis*	Host of unidentified termite species; termite is a big problem in the Philippines both in living trees and in structural wood.
4. *Swietenia macrophylla*	Host of *Zeuzera coffeae*; affected stands of mahogany (*Swietenia macrophylla*) and could affect species from the same family (Meleaceae)
5. *Leucaena leucocephala*	Host of *Heteropsylla cubana*; considerably damaged all ipil-ipil stand in the country and could potentially invade other native plants
B. Invertebrates	
1. Big headed ant (*Pheidole megacephalus)*	Displaced most invertebrate faunas; pest to agriculture as it harbours phytophagous insects that reduce crop productivity
2. Fire ant (*Solenopsis geminate)*	Invaded native communities and affected many, or all of the animals and plants in the community; has fiery and painful stings; nests in the soil
3. Jumping plant lice (*Heterophylla cubana)*	Introduced by the typhoon in 1980. It has affected almost all standing *Leucena leucocephala* plantations
4. Leaf miner (*Liriomyza sp.*)	Accidentally introduced with the importation of chrysanthemums: Major pest of potato crops and ornamentals
5. Spiralling whitefly (*Aleurodicus dispeures*)	Affects vegetables and ornamentals. Accidentally introduced with the importation of ornamental kalanchoe in 1970s

Table 1. ...*cont'd.*

Alien Species	Effects to the Ecosystem
6. Mealy bug (*Pseudococcus sp.*)	Affects the coconut in Northern Palawan. Accidentally introduced in 1990 with the importation of hybrid coconut planting materials
7. Riceblack bug (*Scontiniphora coarctata)*	Major problem of rice in Mindanao and Leyte. This bug was introduced through vessels plying the route between the province of Palawan and countries south of the Philippines
8. Potato cyst nematode (*Globodera rastochlensis*)	Accidentally introduced in the importation of potato planting materials. Heavily infesting potato farms in Benguet in the Northern Philippines
C. Animal	
1. Wild pig (*Sus scrofa*)	Causes damage to agricultural crops; outcompeted the indigenous bearded pig (*Barbatus celebensis*)
III. Grassland Ecosystems	
1. Hagonoy (*Chromolaena odorata)*	Considered to be a harmful plant in grasslands because it outgrows or prevents establishment of other species like *Imperata cylindrica*
2. Lantana (*Lantana camara*)	Weed in pasturelands
3. Chinese creeper (*Mikania micranth)*	Kills other plants by smothering them
4. South American shrub (*Pachysachys coccinea)*	Introduced as an ornamental; dominates nature reserves and parks in Luzon
5. *Mimosa pigra*	Invades lowland/upland, agricultural land

Source: Uriarte 2005

2.3 Biosecurity in New Zealand

New Zealand is the first country in the world that enacted a biosecurity law – the Biosecurity Act of 1993. The Act in essence, restated and reformed the law relating to the exclusion, eradication, and effective management of pest and unwanted organisms. Historically, New Zealand's biosecurity effort was directed at protecting land-based primary production which includes agriculture, forestry and horticulture industries; and facilitating international trade in primary products (Sutton, 2003). Jay *et al.* (2003) reported that in the past, biosecurity activities in New Zealand has been successful in protecting the country from economically important organisms however, it was less successful in relation to the protection of the natural environment. A report published by the Parliamentary Commissioner for the Environment (2000) provided a comprehensive analysis of New Zealand's biosecurity system prior to the new system that is currently being implemented in the country. The report was highly critical of

the operational weight placed on economic biosecurity objectives, and the almost total exclusion of marine biosecurity issues. It stated that New Zealand's biosecurity system needs a set of clearly articulated directions, "particularly in relation to native flora and fauna, biodiversity, and ecosystem and public health" (2000: 7). Arguably, a recent study of Jay *et al.* (2003: 121) concluded that "New Zealand's biosecurity policies have been gradually evolving from a narrow focus on production pests to a broader awareness of multiple economic, social, and ecological objectives."

In 2003, the New Zealand Biosecurity Council released its biosecurity strategy. The Council redefined the meaning of biosecurity for New Zealand and it stated that "biosecurity is the exclusion, eradication or effective management of risks posed by pests and diseases to the economy, environment and human health" (Biosecurity Council 2003). The new definition shows that biosecurity in New Zealand has evolved from a narrow focus to a broader awareness of multiple economic, social and environmental objectives (Jay *et al.* 2003). Overall, the Strategy concludes that New Zealand's biosecurity system is well developed however, it also identifies weaknesses in a range of areas. Sutton (2003) highlighted some of these in the government's response to the Strategy. The Strategy seeks continual, incremental improvement in as systematic manner across the biosecurity system. It has not identified any area where activity is totally lacking or performance is drastically inadequate but rather, it has highlighted a series of areas where steady ongoing improvement is needed. The strategy also notes that, at its heart, improving the biosecurity system's performance requires excellence in implementation and management and recognises that this will require substantial efforts and resources. Ultimately, how much can be achieved will be determined by the extent to which society values each of the outcomes to which biosecurity contributes (Sutton 2003).

At present, the current biosecurity system in New Zealand has shifted from a sectoral approach to a broader but integrated whole-of-system approach to biosecurity (MOU 2005). It is also geared towards addressing and managing risks at points of intervention, *i.e.* at pre-clearance[6] and post-clearance[7]. This system will be discussed further in Chapter 5 of this thesis.

2.4 Biosafety in the International Context

The origin of biosafety has its roots in the Convention on Biological Diversity (CBD). Adopted in 1992 under the auspices of the United Nations Environment Programme (UNEP), the Convention is the first global treaty to provide a comprehensive framework that addresses all aspects of biodiversity – ecosystems, species and genetic diversity. It also introduces a new strategy for the biodiversity crisis known as the "ecosystem approach", which aims to reconcile the need for environmental conservation

[6] Management of biosecurity risks before it enters the border or at the border.
[7] Management of 'residual' biosecurity risks, i.e. risks that cannot be managed by pre-clearance activities or that remain after pre-clearance conditions have been met, or where risk is already present within New Zealand.

with concern for economic development (SCBD & UNEP 2003). Today, the Convention is the main international instrument for addressing biodiversity issues. With almost 190 governments signatories as Parties, the convention aims to provide a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources, and the fair and equitable sharing of benefits derived from the use of genetic resources. Biosafety is one of the issues addressed by the Convention. This concept refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognised as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care.

At its second meeting, held in Jakarta on November 1995, the Conference of the Parties (COP2) to the Convention established an open-ended *ad hoc* Working Group on Biosafety to develop a draft protocol on biosafety. The focus of the draft protocol was specifically on transboundary movement of any LMO resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. After several years of negotiations, the Protocol, known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was finalised and adopted in Montreal on 29 January 2000 at an extraordinary meeting of the Conference of the Parties (SCBD 2000). On 11 September 2003 the formal entry into force of the Cartagena Protocol on Biosafety took place and marked the beginning of a new phase in the history of the Protocol (SCBD 2003).

2.4.1 The Cartagena Protocol on Biosafety

The Cartagena Protocol promotes biosafety by establishing practical rules and procedures for the safe transfer, handling and use of GMOs, with a specific focus on regulating movements of these organisms across borders, from one country to another (SCBD 2003). This system features two separate sets of procedures, one for GMOs that are to be intentionally introduced into the environment, and one for GMOs that are to be used directly as food, or feed, or for processing. Both sets of procedures are designed to ensure that recipient countries are provided with the information they need for making informed decisions about whether or not to accept GMO imports. Governments exchange this information through a Biosafety Clearing House and base their decision on scientifically sound risk assessments and on the "precautionary approach" (SCBD & UNEP 2003).

The entry into force of the Biosafety Protocol presents a new challenge. Like other international agreements, implementation of the requirements of the Protocol will be an on-going and iterative process. Zedan (2003) stated that the primary step is the translation of those requirements into appropriate domestic laws and other practical implementation measures. Countries need to establish a well thought-through biosafety framework that is workable, transparent, and consistent with the

Protocol and other international agreements and eventually start 'working with the Protocol' once they have become Parties (van der Meer 2003, cited in SCBD 2003). However, it is complicated by the lack of shared norms in the governance of biosafety. In India for instance, Gupta (2001) reported that shared norms in biosafety governance were missing. In implementing the Cartagena Protocol, Falkner and Gupta (2004) reported that although the Cartagena Protocol is becoming a global source of rules and norms for GMO trade, there are important elements which need to be negotiated by the Parties in order to make it a comprehensive regulatory system.

There are differences as well in how some countries approach their national policies on biosafety. For example, UNEP-GEF (2004) reported that Myanmar, as well as a number of Pacific Island countries, see biosafety within the context of their national policies on biosecurity *i.e.* together with their plant and animal quarantine, as well as management of invasive species. In the case of Bhutan, Lebanon, Moldova and Romania, they include biosafety within the context of their national policies or plans on biodiversity conservation and environmental protection. The current scenario indicates a need for a better understanding of the whole concept of biosafety in relation to biosecurity and other fields.

2.5 Biosafety in the Philippines

The Philippines was the first country in the ASEAN region to develop a biosafety system (NCBP 1990). In 1987, scientists from the University of the Philippines at Los Baños (UPLB), International Rice Research Institute (IRRI), and Department of Agriculture (DA) constituted themselves into an *ad hoc* Committee on Biosafety. The *ad hoc* Committee lobbied before the national government for the formulation of a national policy on biosafety and the creation of a technical body to draft guidelines that would ensure experiments where genetic manipulation is involved do not pose unacceptable risks to human health and the environment (NCBP 1990).

These efforts and policy initiatives of the scientific community subsequently led to the creation of the National Committee on Biosafety of the Philippines (NCBP). In October 1990, former President Corazon Aquino issued Executive Order (EO) No. 430 constituting the NCBP, a multi-disciplinary, inter-agency, scientific and technical advisory committee tasked with "undertaking the study and evaluation of existing laws, policies and guidelines on biotechnology; and recommending measures for its effective utilisation and prevention of possible harmful effects on the environment" (Ochave & Estacio 2001).

In the international arena, the Philippines is a member-party to several international agreements which impact on the implementation of biosafety practices in the country. It is a member-party to the Convention on Biological Diversity (CBD) having signed it in 1992 and subsequently ratified it in

October 1993. In May 2000, the Philippines signed the Cartagena Protocol on Biosafety to the CBD; the country however, has not ratified the Protocol and therefore is not a Party to it yet, since its entry into force on 11 September 2003. According to Halos *et al.* (2004) it may still take time for Presidential ratification of, and Senate concurrence of the Cartagena Protocol. In the last two meetings of the Conference of the Parties serving as the Meetings of the Parties (COP/MOP – 1 & 2) held in Kuala Lumpur, Malaysia and Montreal, Canada, respectively, the Philippines remained as an observer.

In October 2002, the Philippines became a beneficiary of the UNEP/GEF Global Project on Development of National Biosafety Frameworks (NBF). The NBF Project aims to prepare countries for the entry into force of the Cartagena Protocol on Biosafety. A major output of the Project in the Philippines is the development of its NBF.

In terms of specific research conducted in line with biosafety in the Philippines, Aerni (2002) conducted a study comparing stakeholders' attitudes toward the risks and benefits of agricultural biotechnology in the Philippines and Mexico. In particular, Aerni found that stakeholders in the Philippines and Mexico were concerned about the potential impact of transgenic crops on both countries' rich biological diversity. It was also noted in the Aerni study that the stakeholders are not convinced that the national biosafety guidelines will be implemented properly in the two countries.

2.6 Biosafety in New Zealand

Prior to 1996, there was no law in New Zealand specifically dealing with the release of GMOs into the environment. In 1988, the Minister for the Environment set up a body called the Interim Assessment Group (IAG), which reviewed proposals to field test or release GMOs but had no statutory basis. Review was mandatory for government-funded research and voluntary for privately-funded research ((Royal Commission on Genetic Modification 2001).

The Hazardous Substances and New Organisms Act of 1996 (HSNO) established a regulatory regime for new organisms, including GMOs, to be administered by a new agency, the Environmental Risk Management Authority (ERMA). HSNO's rules on new organisms came into effect in 1998. Under HSNO, applications to develop or test a new organism in containment, or to release it into the environment, are reviewed by ERMA staff and decided upon by the Authority, a six- to eight-member quasi-judicial board whose members are appointed by the Minister for the Environment.

When the HNSO Act was enacted in 1996, it established a regulatory regime for new organisms, including GMOs, to be administered by a new agency which is the ERMA. The HSNO rules on new organisms came into effect in 1998 and currently, all GMO applications are considered new organisms and so are under ERMA's jurisdiction. Although ERMA has jurisdiction over applications to

intentionally release a GMO, it lacks the operational capacity to enforce its decisions under HSNO, so enforcement is handled by MAF under the provisions of HSNO Amendment Act of 2003.

In the years 2000 to 2001, the New Zealand government appointed an independent Royal Commission on Genetic Modification to preside over one of the most ambitious, wide-ranging public debates on the question of genetic modification ever attempted anywhere (Pollak 2003). The Royal Commission heard testimonies from hundreds of interested groups and experts, as well as the views of thousands of members of the general public.

Pollak (2003) provides a brief summary of the process that the Royal Commission went through which included: scoping meetings, formal hearings, public meetings, public submissions, Māori consultation programmes, youth forums and public opinion surveys. The outcomes of these public consultations were succinctly summarized by Pollak (2003: i): "The Royal Commission's work supports a number of observations and conclusions about public participation. Among other things, it demonstrated the usefulness of having several mutually enforcing streams of public consultation, and of making efforts to overcome cultural, temporal and geographic barriers to foster wide participation. The Royal Commission's conclusions departed significantly from the anti-GM views held by the majority of the general public. What, then, was accomplished by consulting the public? The Royal Commission process helped to stimulate a debate that likely enhanced public understanding. Although many disagree with the current direction of policy, the Royal Commission's report clearly helped the Government to shape policies that acknowledge and reflect many areas of public concern."

In October 2003, Parliament enacted legislation amending the HSNO Act. The amendments enacted into law many of the recommendations of the Royal Commission. Key amendments to the HNSO Act will be presented in Chapter 4.

CHAPTER 3

RESEARCH METHODOLOGY

The research questions of this thesis required a methodological approach that could accommodate a focus on in-country systems, policies, regulations, issues and influences on process and outcome. The primary methodology used was the integrated element of qualitative research approach to two country case-studies on the way biosecurity and biosafety is practised. The researcher employed the triangulation technique of in-depth interviews, secondary/archived documents, and observation in informing the case-study analysis.

3.1 The Research Locale

This study drew on the experiences of the Philippines and New Zealand in terms of the biosecurity and biosafety systems in place in both countries and how they operate. This study was inspired by the intrinsic parallelism between the countries with respect to a number of areas presented in the following sections below.

3.1.1 Country Profile

The Philippines

The Philippines is an archipelago comprising 7,107 islands (depending on whether it is high tide or low tide) lying about 805 km off the southeast coast of Asia. It is located on the Asia-Pacific "Ring of Fire" and has a total land area of approximately 300,000 square kilometres (circa 30 million hectares) two thirds of which are mountainous with narrow coastal lowlands. The islands are grouped into three large groups: Luzon, Visayas, and Mindanao. The capital Manila is located in Luzon which is the major northern island[8].

The country's encounter with the Western world started after Fernando Magallanes, the Portuguese navigator serving the King of Spain, landed on its shore on 16 March 1521. Before that, however, the Filipinos had a civilisation of their own and had been trading partners of the Chinese, the Arabs, and

[8] United States Department of State Bureau of East Asian and Pacific Affairs' Background Note: Philippines. www.statc.gov/r/pa/ei/bgn/2794.htm. Date retrieved: 30 September 2005.

the people of neighbouring countries for centuries. The Philippines was under Spanish control from 1565-1898, the United States from 1898-1942, and Japan from 1942-1945[6].

As of July 2005, the projected population of the Philippines was estimated to be around 85.2 million people[9]. There are 87 native languages and dialects spoken, with Filipino as the national language, and English as the second language spoken by nearly half of the population including nearly all professionals, academics, government and non-government workers[10].

The Philippines is a republic and follows a presidential form of government. The President is elected for a period of six years, is the Head of State, and Head of the Executive Branch of the Government. The Legislature is headed by the Senate President in the Upper House and by the Speaker of the House of Representatives in the Lower House. The Chief Justice of the Supreme Court heads the Judiciary. The country is composed of 15 administrative regions, which include 78 provinces, and 61 chartered cities[6].

The Philippines has a Gross Domestic Product of US $84.2 billion in 2004 with an annual growth rate of 6.1%. Its per capita income in 2004 was US $976. Agriculture accounts for a quarter of Philippines' Gross Domestic Product (GDP). The main agricultural products include rice, coconut products, sugar, corn, pork, bananas, pineapple products, aquaculture, mangoes, and eggs, among others. The natural resources of the country include copper, nickel, chromium, iron, cobalt, silver, gold and natural gas[6].

The Philippines is considered as one of the 17 mega diverse countries in the world. These countries hold about 70 percent of the world's total diversity in flora and fauna. In the Philippines alone, there are over 52,000 species. Of these, 13,500 are plants comprising 5 percent of the world's total flora. About 68 percent of the country's reptiles, 78 percent of amphibians, 64 percent of the mammals and 44 percent of birds are considered unique in the Philippines. In terms of uniqueness or endemism, many of the country's species rank in the top ten in the world. Considering land density and density of flora and fauna, the Philippines may even be considered to be the most mega diverse country[11].

New Zealand

New Zealand is located in the southwest Pacific Ocean midway between the Equator and the South Pole, approximately 1,600 kilometres southeast of Australia. It has a total land area of approximately 270,500 square kilometres (circa 27.05 million hectares), about the size of Japan, Britain and Italy.

[9] National Statistics Office (NSO) 2005. www.census.gov.ph. Date retrieved: 03 October 2005.
[10] The Philippine Government's Department of Tourism. www.tourism.gov.ph. Date retrieved: 26 September 2005.
[11] Source: National Economic and Development Authority 2004. Medium Term Philippine Development Plan 2004 – 2010.

The country is made up of two big islands - the North Island and South Island, and a number of smaller islands. It has a highly varied landscape from snow-capped mountain ranges and hill country to lowland and coastal plains; and archaeological evidence indicates that New Zealand was populated by fishing and hunting people of East Polynesian ancestry perhaps 1,000 years before Europeans arrived[12].

In 2004, an estimated 4 million people live in this temperate to subtropical country with an annual population growth of 1.3%. Seventy five percent of the total population is of European descent, 15% Maori, and 6% other Polynesians and 4% Asians. English is spoken by the majority and Maori is spoken by less than 15% of the population. New Zealand has a 99% literacy rate with 100% of children and adolescents from 6 years old to 16 years old attending school. It is a largely secular state, although the majority are considered Protestants and 15% are Roman Catholics[13].

New Zealand has a parliamentary system of government closely patterned on that of the United Kingdom and is a fully independent member of the Commonwealth. Executive authority is vested in a Cabinet led by the Prime Minister, who is the leader of the political party, or coalition of parties holding the majority of seats in Parliament. All cabinet ministers must be members of Parliament and are collectively responsible to it[9].

The unicameral Parliament (House of Representatives) has 120 seats, six of which are currently reserved for Māori elected on a separate Māori roll; however, Māori may also run for, and have been elected to, non-reserved seats. Members of Parliament are elected for a maximum term of three years, although elections can be called sooner[9].

The Judiciary consists of the Supreme Court, Court of Appeal, the High Courts, and the District Courts. New Zealand law has three principal sources: English common law, certain statutes of the United Kingdom Parliament enacted before 1947, and statutes of the New Zealand Parliament. In interpreting common law, the courts have been concerned with preserving uniformity with common law as interpreted in the United Kingdom[9].

New Zealand has a Gross Domestic Product of US $99.69 billion in March 2005 with an annual growth rate of 4.8%. Its per capita income in 2004 was US $23,900. The country is rich in timber, natural gas, iron sand, and coal. Its chief products are wool, meat, dairy, and forestry[9].

New Zealand's biodiversity is unique and is considered internationally important. High percentages of New Zealand's indigenous species are endemic (they are found nowhere else on earth) – a result of

[12] United States Department of State Bureau of East Asian and Pacific Affairs' Background Note: New Zealand. www.state.gov/r/pa/ei/bgn/35852.htm. Date retrieved: 30 September 2005.
[13] Statistics New Zealand Quick Facts. www.stats.govt.nz. Date retrieved: 26 September 2005.

isolated evolution and the diversity of New Zealand's land and seascapes. This level of endemism is remarkable internationally. New Zealand's is home to the world's only flightless parrot (kakapo); a bird with nostrils at the end of its beak (kiwi); a primitive frog that lays eggs that hatch adult frogs (*Leiopelma* species); and many other exceptional species. The ecosystems in which these species live are also highly distinctive such as the kauri forests of the northern North Island, and the braided river systems of the eastern South Island[14].

3.2 Research Framework

This study followed a qualitative research framework. **Figure 1** shows the flow of methods and techniques employed in this study.

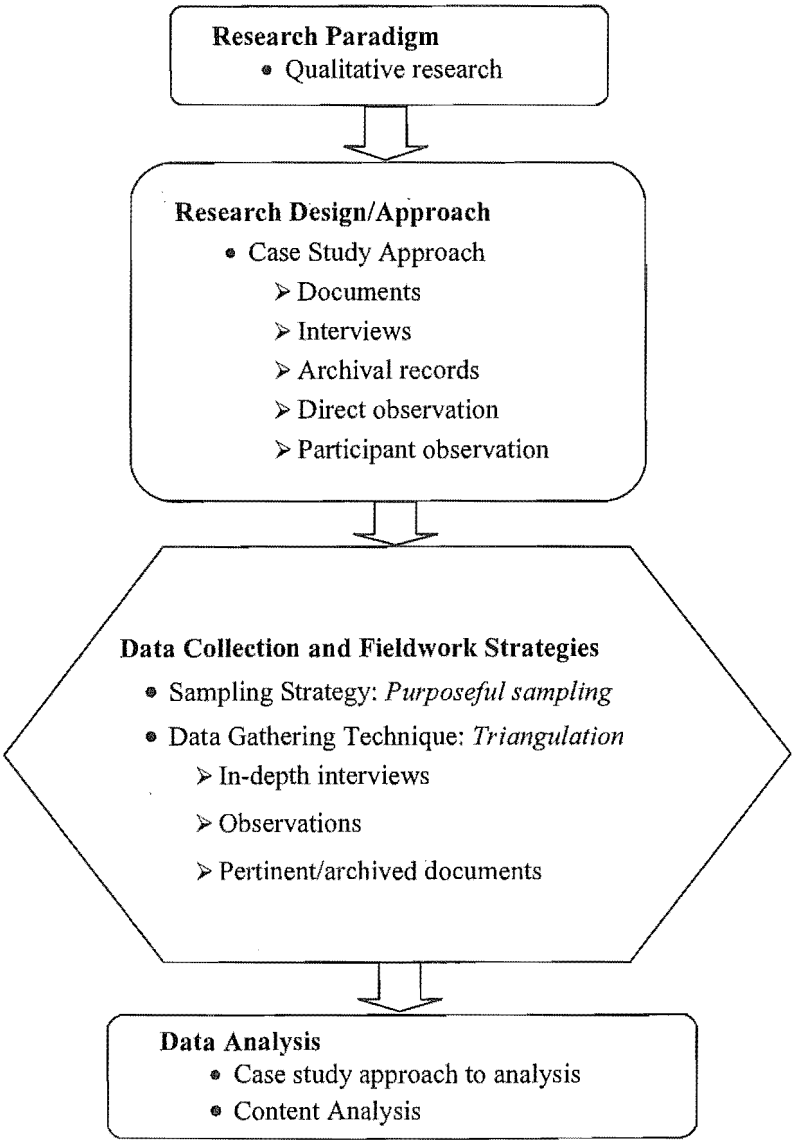

Figure 1. Research Framework of the Study

[14] Source: The New Zealand Biodiversity Strategy, February 2000.

3.2.1 Research Paradigm

This study followed the qualitative research paradigm primarily because the nature and context of this study dealt more with the two countries' experiences of policy, regulatory regimes and framework in view of the cross cutting topics of biosecurity and biosafety. Qualitative research aims to provide an in-depth understanding of people's experiences, perspectives and histories in the context of their personal circumstances or settings (Strauss & Corbin 1990; Taylor & Bogdan 1998, Patton 2002, Spencer *et al.* 2003). "Among many distinctive features, it is characterised by a concern with exploring phenomena from the perspective of those being studied; with use of unstructured methods which are sensitive to the social context of the study; the capture of data which are detailed, rich and complex; a mainly inductive rather than deductive analytic process; developing explanations at the level of meaning or micro-social processes rather context-free laws; and answering '*what is*', '*how*' and '*why*' questions" (Spencer *et al.* 2003: 3).

3.2.2 Research Design/Approach

This study utilised the case study approach in conducting the research. "A case study reports on a 'phenomenon' within, but separate from, its larger context. The phenomenon studied may be a culture, society, community, subculture, organisation, group or institution, beliefs, practices, or interactions or almost any other aspect of human existence (Jorgensen 1989: 19)." In particular, this study looked at the national-level context of the current approaches, practices, frameworks, institutions involved, and norms within the biosecurity and biosafety spectrum. The researcher explored in depth the national policies, programmes, and processes bound by time and activity; and collected rich-text information using a variety of data collection procedures over a period of time. This case study was further informed by a good case study strategy provided by Yin (1994, 2003) and Patton (2002), which comprises encompassing methods and specific approaches to data collection and organisation, and data analysis. The case study in this sense was not merely a design feature alone nor just a data collection tactic (Stoecker 1991) but a comprehensive research strategy (Yin 1994). It follows a systematic process to gather information about each case of interest; and each case can be treated as a process and a product of analysis (Patton 2002).

There are six important methods and sources of evidence used in a case study. These are: documentation, interviews, archival records (such as service records, organisational records, maps, charts and survey data), direct observation, participant observation, and physical or cultural artefacts (such as tools, instruments or works of art) (Yin 1994). This case study utilised almost all the methods provided by Yin except physical or cultural artefacts. Throughout the process of employing these methods, the researcher endeavoured to develop a range of personal skills, most of which are

emphasized by Yin (1994), including being able to set the tone of the initial conversation preceding the actual/formal interview; being able to ask the relevant questions in the manner that goes with the flow and context of the interview; being a good listener; being adaptive and flexible; being able to access pertinent information and archival documents; having firm grasp of the issues under study; and being unbiased by preconceived notions.

3.2.3 Data Collection and Fieldwork strategies

Sampling Strategy

Purposeful sampling was used as the sampling technique in this research. This was used because in purposeful sampling "cases for study (e.g. people, organisations, communities, cultures, events, critical incidences) are selected because they are 'information rich' and illuminative, that is, they offer useful manifestations of the phenomenon of interest. Sampling, then is aimed at insight into the phenomenon, not empirical generalisation from a sample to a population" (Patton 1990, 2002, 2003). Among purposeful sampling strategies the researcher, most of the time, employed *opportunistic or emergent sampling*. This means following new leads during field work, taking advantage of the unexpected, and focusing more on flexibility. Fieldwork often involves on-the-spot decisions about sampling to take advantage of new opportunities during actual data collection. In particular, the use of the sampling technique for this study was informed by Patton (1990, 2002) who emphasized that "unlike experimental designs, emergent qualitative designs can include the option of adding to a sample to take advantage of unforeseen opportunities after fieldwork has begun." Being open to following wherever the data lead is a primary strength of qualitative fieldwork strategies. This permits the sample to emerge during fieldwork. Opportunistic, emergent sampling takes advantage of whatever unfolds as it unfolds (Patton 1990, 2002).

Data Gathering Technique

The triangulation method was employed in gathering the data needed for this study. Triangulation is the use of multiple methods to generate more valid results (Denzin & Lincoln 1994, Silverman 2000, 2005). The researcher used the triangulation of three kinds of qualitative data, including in-depth interviews, observations and pertinent documents. Pertinent documents are those documents which are considered important, relevant and supplementary in view of the topic(s) under study (Patton 2002).

In-depth Interviews

Open-ended questions and probes yield in-depth responses about people's experiences, perceptions, opinions, feelings, and knowledge (Patton 2003). The researcher conducted in-depth face-to-face interviews, telephone interviews and email interviews in the Philippines and New Zealand. Most of the interviews carried out by the researcher were face-to-interviews some of which were considered to be "elite interviewing" (Hertz and Imber 2005, cited in Gupta 2001). They were referred to as elite interviews in the sense that the interviewees were in the higher echelon in terms of their positions and/or held sensitive posts in the government, private sector or in any organisation or institution they represented. One important element of the interviews that was employed by the researcher was assuring the interviewees of the 'strict confidentiality' of the data and information gathered. Fieldwork and interviews in the Philippines (mostly in Manila) were conducted in October and November of 2004, and in the months of July and August 2005 in New Zealand (mainly in Wellington and Christchurch). There were two telephone interviews as well carried out by the researcher in the month of September 2005; one in the Philippines and one in Wellington New Zealand. At least four email interviews were sent to interviewees located in Wellington and Manila, two of which were follow-up questions from the earlier face-to-face interviews that were conducted. During the interviews, most of the interviewees were forthcoming and responsive.

Observation

Observation is described by Patton (2002) as fieldwork descriptions of activities, behaviours, actions, conversations, interpersonal interactions, organisational or community processes, or any other aspect of observable human experience. The data consists of field notes and rich, detailed descriptions, including the context within which the observations were made. The researcher employed 'direct observation' during interactions and conversations with the interviewees. Also, in New Zealand, the researcher attended three major conferences: the first was an International Conference of mostly entomologists and ecologists in August 2003 in Hanmer, the second was an APEC Science Ministerial Meeting held in Christchurch in March 2004, and the third was the Second National Biosecurity Summit held in Auckland in November 2004. In the course of these meetings the researcher observed, especially during workshops and panel discussions. Whilst conducting fieldwork in the Philippines, the researcher took the opportunity to participate in one symposium and a technical briefing. The first was a symposium on 'Biodiversity and Food Security' held in Quezon City in Metro Manila in October 2004; whilst the second was a 'Technical Briefing of the Chief of Staffs of the Congress and Senate Committees on the Environment' regarding the proposed National Biosafety Framework and the potential ratification of the Cartagena Protocol on Biosafety. These events proved to be an engaging

experience for the researcher and enabled direct observation of the activities in these meetings to be made.

Pertinent/Archived Documents

Documents according to Patton (2002) can be written documents and other documents from organisational, clinical, or program records; memoranda and correspondence; official publications and reports; personal diaries, letters, artistic works, photographs, and memorabilia; and written responses to open-ended surveys. Data consists of excerpts from documents captured in a way that records and preserves context. In addition to in-depth interviews and direct observations, the researcher also relied on archived documents and supplementary evidence gathered during fieldwork in the Philippines and New Zealand. These documents included, among others: Statements of Intents (SOI), government reports, draft frameworks, progress reports, workshops proceedings, conference proceedings, government published documents, position papers, technical magazines, cabinet papers, technical pamphlets, unpublished manuscripts and media reports. They were either sourced from the internet or directly obtained from the individuals or organisations concerned. There were two occasions in New Zealand where the researcher requested the information through the 'Official Information Act'. The archived documents obtained in the process of conducting this research proved to be a key source of important data and information used in this study.

The researcher has also drawn upon secondary literature in order to explore the larger context within which biosecurity and biosafety undertakings occur.

3.2.4 Data Analysis

Throughout the duration of this study a large amount of data was gathered and obtained. The data consisted of transcripts of tape-recorded interviews, handwritten field notes, organisational reports, publications, pamphlets, booklets, electronic journals, and a collection of associated documentation. Seeking 'meaning' from the data collected is the core of data analysis. In qualitative research, data analysis is an "ongoing process involving continual reflection about the data" (Creswell 2003: 190). The management of the large volumes of qualitative data had the potential to cause problems for the eventual analysis. To avoid an overwhelming amount of information at the end of the research process, data were progressively analysed. This occurred as the data were collected from original sources, reviewed, organised and managed, which included the transcribing of all interviews, and scanning and selecting relevant information throughout the write-up process. The themes of the research emerged during this analytical process whilst the process itself was equally shaped by the respective questions and descriptive details pulled together in each case study for the two countries.

Transcription of the interviews was carried out by the researcher personally for two vital reasons: (1) So that the transcription process can be an initial form of analysis seeking meaning and context along the way (2) So that the confidentiality of the transcribed information is assured. Likewise, in the presentation of the responses/quotes made by the interviewees, names were not identified as the researcher and each interviewee agreed on a 'strict confidentiality' accord. The researcher endeavoured to translate all responses spoken in Filipino/Tagalog (during interviews in the Philippines) into English.

The particular method used in the analysis was a combination of case study approach and content analysis which are further discussed in the following sections below.

Case Study Approach to Analysis

The case study approach was one of the methods used in the analysis of data. This approach to qualitative analysis constitutes a specific way of collecting, organising, and analysing data; in that sense it represents an analysis process. The purpose is to gather comprehensive, systematic, and in-depth information about each case of interest. The analysis process results in a product – a case study. Thus the term case study can refer to either the process of analysis or the product of analysis, or both (Patton 1990, 2002, 2003). In the case studies conducted by the researcher, each case study was treated as the process and product of analysis.

Content Analysis

Content analysis usually refers to analysing text (interview transcripts, diaries, or documents) rather than observation-based field notes. More generally, however, content analysis is used to refer to any qualitative data reduction and sense-making efforts that take a volume of qualitative materials and attempt to identify core consistencies and meanings. Of particular relevance, case studies can be content analyzed (Patton 2002). Content analysis involves identifying, categorising, classifying and labelling the primary patterns in the data. This essentially means analyzing the core content of interviews and observations to determine what is significant (Patton 1990, 2002, 2003). In such a process, the researcher is mindful of the recommendations made by Hammersley & Atkinson (1983, 1995) and Bryman & Burgess (1994), that in doing the analysis one should immerse oneself in the data and seek out patterns, identifying possibly surprising phenomena, and being sensitive to inconsistencies, such as divergent views offered by different groups or individuals. The analysis process was further informed by Tomlinson (2003: 48-49), that "each stage of analysis required elements of 'data reduction', which is where less information was transferred from each stage of data

reorganising." The researcher focused analysis through continued mutual interaction between the reduction of data, and the continued display and redisplay of data. In conjunction with filtering and reduction techniques, the researcher was heedful of the research objectives as the eventual thesis findings unfolded.

3.3 Research Evaluation

Validity refers to the extent to which "an empirical measure adequately reflects real meaning of the concept under consideration" (Babbie 1995: 127). According to Creswell (2003) validity should be seen as the "strength of qualitative research"; it should be used in establishing whether the findings are accurate from the viewpoint of the researcher, participant or the readers of an account. Hence Creswell (2003: 196) enumerated eight primary strategies to check the accuracy of the findings which included triangulation; member checking; use of rich, thick description; clarification of bias; presentation of negative or discrepant information; spending a prolonged time in the field; use of peer debriefing; and the use of an external auditor. In seeking to achieve validity in this study, the triangulation method, consultation with the supervisor, peer consultation and a thorough consideration of the data gathered were adopted. Moreover, the researcher endeavoured to present a rich, thick description of the findings and has clarified the bias that may impinge on analysis of the data.

3.4 Researcher's Role/Bias

In qualitative research, Creswell (2003) indicated that the role of the researcher as the main data collection instrument requires the identification of the personal values, biases and assumptions. The researcher before starting this study was working on tropical tree breeding research for a period of six years in a private company in the Philippines. It must be further emphasized that the researcher had no involvement in government nor in any institutions or organisations either in the Philippines or New Zealand from the time that this study commenced up to the time it culminated (*i.e.* the third quarter of 2003 and the third quarter of 2005, respectively). However, as Miles and Huberman (1994) pointed out, it is impossible to achieve a clean theoretical slate and to enter the research field with no preconceived notions. The researcher brought to this study a notion that New Zealand is definitely advanced in its biosecurity, but not too advanced in dealing with biosafety; on the other hand, the Philippines may not have a biosecurity system to speak of, but is advanced when it comes to biosafety matters. Whilst the researcher may have brought certain biases to this study, every effort was made to ensure objectivity in the presentation of the results and its analysis.

3.5 Ethics

The researcher made a considerable effort to ensure that the ethical dimension of the research process was observed and practised to its highest degree. The researcher before conducting each interview sought the interviewee's permission to record the interview on a digital recorder and on tape; assured confidentiality of their responses; and respected and appreciated the length of time each interviewee was able to lend for such interview. In the discussion of the findings, quotes were not attributed to individuals by name.

CHAPTER 4

BIOSECURIY AND BIOSAFETY SYSTEMS, POLICIES AND REGULATIONS IN THE PHILIPPINES

This chapter profiles and outlines the existing biosecurity and biosafety policies, laws and regulations in the Philippines. It also elucidates the existing mechanisms, and the governance and regulatory frameworks in place in the country.

4.1 Biosecurity Systems, Polices and Regulations

4.1.1 Existing Policies/Laws

This section profiles and outlines the existing policies and legislation relevant to biosecurity[15] in the Philippines.

The **Philippine Agenda 21** is the country's National Agenda for Sustainable Development. It serves as the country's policy framework and strategy for sustainable development. Of particular relevance to this study, the Philippine Agenda 21 states that "the benefits of modern biotechnology in producing revolutionized products that increase productivity and value must not compromise the ability of the future generations to meet their own needs." The significant features of the Philippine Agenda 21 include:

(a) the realization of the continuing deterioration of the natural and social environment;

(b) a vision of "appropriate (not maximum) productivity" within the limits of the natural environment's carrying capacity;

(c) adoption of a policy mix of market-based instruments and command-and-control measures as techniques to induce changes in production and consumption patterns; and

(d) adoption of social marketing approaches in the effort to inform, educate and communicate the imperative of sustainable development to the public at large to effect a reorientation of fundamental societal values.

[15] Since the term biosecurity is not yet adopted in the Philippines, the terms used (to determine relevant policies and laws) include, among others: quarantine, pests, diseases, plants, animals, exotic species, invasive alien species, and pest management.

In fisheries, the **Fisheries Code**[16] declares that the policy of the State, is among others, "to ensure the rational and sustainable development, management and conservation of the fishery and aquatic resources consistent with the primordial objective of maintaining a sound ecological balance, protecting and enhancing the quality of the environment." The introduction of foreign finfish, mollusks, crustaceans or aquatic plants in Philippine waters without a sound ecological, biological and environmental justification based on scientific studies shall not be allowed subject to the biosafety standard as provided for by existing laws.[17] However, the Department of Agriculture (DA) may approve the introduction of foreign aquatic species for scientific/research purposes. The law also provides for conservation and rehabilitation measures for rare, threatened and endangered species, and banning of the fishing and/or taking of rare, threatened and/or endangered species, including their eggs/offspring as identified by existing laws. The fisheries policy puts a premium on aquaculture as a major source of fishery products in the future. Biotechnology offers huge potential benefits in increasing the yield of aquaculture, as well as contributing to the conservation of threatened species.

The **Republic Act 9147**, otherwise known as the Wildlife Resource and Conservation Act enacted in the year 2001, regulates the collection, possession, and/or local transport of wildlife, their by-products and derivatives including the introduction of exotic wildlife into the country (which are subject to trade, are cultured, maintained, and/or bred in captivity or propagated in the country) by requiring an authorisation or clearance from the Secretary of the Department of Environment and Natural Resources (DENR) or the authorised representative. Further, it provides that the collection of wildlife by indigenous people may be allowed for traditional use but not for trade, on condition that collection and utilisation for the said purpose shall not cover threatened species. In the case of exotic species, the Act states that in no case shall exotic species be introduced into critical areas and designated critical habitats (Section 25) and into protected areas covered by Republic Act No. 7586 (NIPAS Act). In cases where introduction is allowed, it shall be subject to an environmental impact study which shall focus on the bioecology, socioeconomic and related aspects of the area where the species will be introduced. The Proponent shall also be required to secure prior informed consent from local stakeholders.

The **Presidential Decree No. 936 (PD 936)** of 1976 established the National Crop Protection Centre (NCPC) within the College of Agriculture, University of the Philippines in Los Baños, and seven other Regional Crop Protection Centres within the Bureau of Plant Industry (BPI). The law created the NCPC in response to the need of the country to have a unified approach to research, training and

[16] Republic Act No. 8550 (1998).
[17] Fisheries Code, sec. 10.

extension programmes in crop production. Section 1 of PD 936 mandates the NCPC and the other regional centres to perform specific functions such as:

(a) undertaking problem analyses, development research and planning required to develop crop protection systems against pests of major economic crops;

(b) developing and implementing manpower training programs designed to upgrade the pool of manpower required to meet the complex pest control needs of the country;

(c) undertaking information exchange and extension to provide farmers and the public with coordinated information about the varied facets of pest control and to emphasize the urgent need for safe and effective pest control practices;

(d) establishing adequate linkages between research and operational phases at the farm level in order to ensure that the changing research needs for operational activities are based on the most recent and applicable research findings; and

(e) providing scientific advice to government planners for the formulation of policies and regulatory programs necessary for dealing with the complex pest control technologies essential for the protection of crops.

Under the **Seed Industry Development Act,**[18] the State declares it a policy to promote and accelerate the development of the seed industry and, for this purpose, conserve, preserve and develop the plant genetic resources of the nation. It creates the National Seed Industry Council, composed of representatives from the government and private sectors, whose main function is to formulate policies that will stimulate plant breeding activities for the development of the genetic resources of the country. It also institutes a National Seed Quality Control Service, to formulate and develop plans and programs on seed quality control services and activities on seed testing, plant/seed material confirmation and other quality control schemes. The law is complemented by the **High-Valued Crops Development Act**[19] which mandates the state to develop high-value crops as export crops that will significantly augment the foreign exchange earnings of the country, through an all-out promotion of the production, processing, marketing and distribution of high-value crops in suitable areas of the country. It tasks the Department of Agriculture with establishing experimental stations and seed farms for the development of varieties suitable for the agro-climactic conditions of the area, and markets that will provide greatest value added to high-value crops. Both laws do not exclude modern biotechnology techniques as a means for crop development or for improving seed quality.

[18] Republic Act No. 7308 (1992).
[19] Republic Act No. 7900 (1995).

The **Revised Forestry Code**[20] reorganized certain related offices into the Bureau of Forest Development, with the following mandate: to be responsible for the protection, development, management, regeneration, and reforestation of forest lands; the implementation or multiple use and sustained yield management in forest lands; the protection, development and preservation of national parks, marine parks, game refuges and wildlife; the implementation of measures and programs to prevent *kaingin* and managed occupancy of forest and grazing lands; and the enforcement of forestry, reforestation, parks, game and wildlife laws, rules and regulations, among others. It provides incentives to qualified persons engaged in industrial tree plantation, tree farming and/or agro-forest farming. However, it reserves the regulation of mining operations in forest lands to mining laws, rules and regulations, with the only *caveat* that the protection, development and utilization of other surface resources be given due regard. The law is relevant in that GM trees may be used for higher timber yields or greater carbon sequestration abilities, the introduction of which may pose risks to natural stands.

The **NIPAS Act**[21] establishes a National Integrated Protected Areas System (NIPAS), which shall encompass outstanding remarkable areas and biologically important public lands that are habitats of rare and endangered species of plants and animals, biogeographic zones and related ecosystems, whether terrestrial, wetland or marine, all of which shall be designated as protected areas. It provides for categories of protected areas (PAs):

(a) strict nature reserve;

(b) natural park;

(c) natural monument;

(d) wildlife sanctuary;

(e) protected landscapes and seascapes;

(f) resource reserve;

(g) natural biotic areas; and

[20] Presidential Decree No. 705 (1975, as amended in 1978, 1980, 1981, 1987 and 1991).
[21] Republic Act No. 7586 (1992).

(h) other categories established by law, conventions or international agreements to which the Philippine Government is a signatory.

Activities within protected areas are highly regulated especially in strict nature reserves and Natural Parks. Thus, the release of GM products is most likely prohibited within the area.

The **Executive Order No. 247**[22] prescribes guidelines and establishes a regulatory framework (the Inter-Agency Committee on Biological and Genetic Resources) for the prospecting, for scientific and commercial purposes, of biological and genetic resources, their by-products and derivatives. The Committee is tasked, among others, with ensuring that no biological and genetic materials are taken from the Philippines and exported abroad except under a valid Research Agreement; and to study and recommend appropriate laws on the utilization of biological and genetic resources including new laws on intellectual property rights.

The **Animal Welfare Act**[23] regulates the establishment and operations of all facilities utilized for breeding, maintaining, keeping, treating, or training of animals either as objects of trade or as household pets. It provides that only adequate, clean and sanitary establishments of animals that will not be used for, nor cause pain and/or suffering to the animals shall be issued certificates of registration and allowed to operate. It prohibits the killing of any animal other than cattle, pigs, goats, sheep, poultry, rabbits, carabaos, horses, deer and crocodile, except when, among others, the animal is killed after it has been used in authorized research or experiments. It declares that every person has the duty to protect the natural habitat of wildlife. The destruction of said habitat is considered a form of cruelty to animals and its preservation is a way of protecting the animals. The application of modern technology to modify animals must take into account the provisions of this Act.

The **Indigenous Peoples Rights Act (IPRA)**[24] recognises, protects, and promotes the rights of ownership and possession of indigenous cultural communities and indigenous peoples (ICCs/IPs) to their ancestral lands and domains, including the right to manage and conserve natural resources within the territories, and the right to negotiate the terms and conditions for the exploration of these natural resources for the purpose of ensuring ecological and environmental protection and conservation measures, pursuant to national and customary laws. It affords the ICCs/IPs the right to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, and derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, as well as knowledge of the properties of fauna and flora. The law also affords the ICCs/IPs priority rights in the

[22] Executive Order No. 247 was issued by the President of the Philippines on 18 May 1995.
[23] Republic Act No. 8485 (1998).
[24] Republic Act No. 8371 (1997).

harvesting, extraction, development or exploitation of any natural resources within the ancestral domains.

The revised **Philippine Biosafety Guideline (PBG)** issued by the National Committee on Biosafety of the Philippines (NCBP) in 1998 prescribed guidelines on the planned release of Genetically Modified Organisms (GMOs) and potentially harmful exotic species (PHES). With regard to PHES, the PBG defines it as any exotic species which may constitute significant negative risks to human health and the environment. The guideline mandates that no person or institution shall release into the environment any GMOs or PHES without the prior approval of the NCBP.

Import and Export Laws

The **Presidential Decree No. 1433 (PD 1433)** otherwise known as the Plant Quarantine Law of 1978 authorises the Department of Agriculture (DA) through the Bureau of Plant Industry (BPI) to exercise inspection and certification and/or treatment activities on imported and exportable plant products such as fruits and vegetables. PD 1433 also mandates the BPI to prevent the introduction of exotic pests into the country, to prevent further spread of existing plant pests and enforce phytosanitary measures for the export of plants, plant products and regulated articles.

The **Republic Act 3639 (RA 3639)** established the Bureau of Animal Industry (BAI) and empowered it to prescribe standards for quality in the manufacture, importation, labelling, advertising, distribution and sale of livestock, poultry, meat products, dairy products and animal feeds and veterinary supplies in the country. The Act tasked the BAI with preventing, controlling, containing and eradicating communicable animal disease by regulating the flow of animals and animal products in the country.

The **Presidential Decree No. 7 (PD 7)** authorises the National Meat Inspection Commission (NMIC) to implement policies and procedures governing post production flow of livestock, meat and meat products both locally produced and imported through the various stages of marketing. The Law instructs the NMIC to supervise the operations of abattoirs and meat establishments and conducts ante- and post-mortem inspections of meat. The meat Import/Export Services of the NMIC ensures that imported or exportable meat and meat products are produced under acceptable conditions and systems.

The **Republic Act No. 123 (RA 123)** prescribed the reorganisation and operation of the Bureau of Quarantine. The Act also positioned the Bureau of Quarantine within the category of first-class bureau under the Department of Health (DOH). Section 2 of RA 123 set the jurisdiction and function of the Bureau of Quarantine. It states that the examination at ports of entry and airports of entry into the Philippines of incoming and outgoing vessels and aircraft should be vested in and be conducted by the

Bureau of Quarantine. Operational mandates of the Bureau include surveillance over sanitary conditions within the aircraft and vessels, as well as over their cargoes, passengers, crews, and all personal effects; and the issuance of quarantine certificates, bills of health, or other equivalent documents. The law empowers the Bureau to have the authority over incoming vessels, including those of the army and navy, both domestic and foreign, their wharfage and anchorage, and over aircraft and airports, insofar as is necessary for the proper enforcement of the provisions of the Act.

4.1.2 Governance and Regulatory Frameworks

It was discussed in Chapter 2 of this thesis that biosecurity is a relatively new term in the Philippines. Hence, in the case of the country's governance and regulatory frameworks, this section will focus on the existing food safety, and plant and animal quarantine systems.

Food Safety Framework

The two main agencies tasked with developing and enforcing food safety standards in the Philippines are the Bureau of Food and Drug (BFAD) under the Department of Health (DOH) and the Bureau of Agriculture and Fisheries Product Standards (BAFPS) of the Department of Agriculture (DA). Under the Food, Drug and Cosmetics Act of 1963, BFAD was made responsible for the safety of processed food products while the Agriculture and Fisheries Modernization Act of 1997 (AFMA) made BAFPS accountable for fresh and primary agricultural and fisheries products (USDA-FAS 2004).

The BFAD's primary function is to ensure the safety, proper handling, efficacy, purity and quality of processed foods, drugs, diagnostic reagents, medical devices, cosmetics and hazardous household substances. The BFAD oversees the control of the manufacture and sale of processed foods, where the major concerns are adulteration and mislabelling of food products. It is responsible for the surveillance of imported food products at legal ports of entry.

The major duties of the BAFPS include formulating and enforcing standards of quality in the processing, preservation, packaging, labelling, importation, exportation, distribution and advertising of fresh and primary agricultural and fisheries products. The BAFPS provides assistance in establishing the scientific basis for food safety, trade standards and codes of practice and harmonizes them with internationally accepted standards and practices. It serves as the National Enquiry Point for Codex Alimentarius and other food safety and standards regulatory bodies. It is in charge of monitoring and disseminating information on international developments in food safety.

Plant and Animal Quarantine Framework

Different regulatory bodies exist in the Philippines in terms of regulating the flow of plants and animals coming in and out of the country. These are often supported by specialist commissions which focus on specific technical matters such as meat inspection, biosafety, etc. The main regulatory bodies monitoring the safety aspects of imported agriculture and food products are the Bureau of Plant Industry (BPI), Bureau of Animal Industry (BAI), and the Bureau of Fisheries & Aquatic Resources (BFAR). All these bureaus are under the jurisdiction of the DA.

The BPI exercises inspection and certification and/or treatment activities on imported and exportable plant products such as fruits and vegetables. It is also mandated by law to prevent the introduction of exotic pests into the country, to prevent further spread of existing plant pests and to enforce phytosanitary measures for the export of plants, plant products and regulated articles (USDA-FAS 2004).

On the other hand, the BAI prescribes standards for quality in the manufacture, importation, labelling, advertising, distribution and sale of livestock, poultry, meat products, dairy products and animal feeds and veterinary supplies in the country. The BAI is also charged with preventing, controlling, containing and eradicating communicable animal diseases by regulating the flow of animals and animal products in the country (USDA FAS 2004).

The BFAR has the administrative responsibility to control fish and other marine products. The Fisheries Post-Harvest Technology Division (FPHTD) of BFAR issues commodity clearances (*i.e.* import permits) and other requirements for the import of fish and fishery products.

All imported food and agricultural products are required to comply with the Philippines' food health and phytosanitary laws. In general, none of these products is allowed to enter the Philippines if it is deemed to be a danger to human life or well-being, either directly or indirectly.

All food and agricultural products, including plant products that enter the Philippines, are required to pass through procedures designed to check that they are not contaminated with any pest and that they are fit for their intended use.

At present, national microbiological standards for food have not yet been established. Philippine food regulations are thus patterned after CODEX Alimentarius Commission guidelines as well as regulations established by the Food and Drug Administration (FDA) of the United States and similar regulatory bodies in other countries.

4.2 Biosafety Systems, Polices and Regulations

4.2.1 Existing Policies and Laws

Policy on Modern Biotechnology

The Republic Act 8435 otherwise known as the **Agriculture and Fisheries Modernization Act (AFMA) of 1997** prescribes measures to modernise the agriculture and fisheries sectors of the country with a view to enhancing profitability and preparing the sectors for the challenges of globalisation. It aims to transform them from a resource-based to a technology-based industry, by ensuring equitable access to assets, resources and services, and promoting higher-value crops, value-added processing, agribusiness activities, and agro-industrialisation. The Act emphasizes that any development in the agriculture and fisheries sectors should be in accordance with the principles of poverty alleviation and social equity; food security; rational use of resources; global competitiveness; sustainable development; people empowerment; and protection from unfair competition. Accordingly, it mandates the DA, in consultation with the farmers and fisherfolk, the private sector, NGOs, people's organizations and appropriate government agencies and offices, to formulate and implement a medium- and long-term comprehensive Agriculture and Fisheries Modernisation Plan focusing on the above-stated principles. In view of product standardisation and consumer safety, the AFMA establishes the Bureau of Agriculture and Fisheries Product Standards (BAFPS) to set and implement standards for fresh, primary- and secondary- processed agricultural and fishery products. More specifically, the coverage of the BAFPS includes standards related to consumer health and safety and efficient trade of raw, fresh, primary and secondary processed agricultural and fisheries products, both food and non-food. The law does not have a specific provision dealing directly with biotechnology or modern biotechnology, but it supports research, development, and use of technology in agricultural production.

Policy Statement on Modern Biotechnology issued by President Gloria Macapagal Arroyo

In July 2001, President Gloria Macapagal Arroyo issued a **Policy Statement on Modern Biotechnology** emphasizing the government policy of promoting the safe and responsible use of modern biotechnology and its products as one of the several means to achieve and sustain food security, equitable access to health services, a sustainable and safe environment, and industry development. It underscores the need for all technologies (including modern biotechnology) to provide farmers with the opportunity to increase their over-all productivity and income, enhance the welfare of consumers, and promote efficiency, competitiveness, and improved quality standards of local industries; all within the paramount objective of attaining safety and sustainable development, including its human, social and environmental aspects.

The Policy Statement also provides directives to respective government departments such as the Departments of Agriculture, Environment and Natural Resources, Science and Technology, Health, Trade and Industry, and other concerned agencies to address the current issues associated with the local and global dimensions and trends of modern biotechnology, including its potential health, environmental and social impacts. Towards this end, they are mandated to:

(1) conduct public consultations with representatives from civil society, government and business;

(2) formulate departmental directives and regulations on the access to, and use of the products of modern biotechnology;

(3) coordinate activities and programs on research, development and application; and

(4) allocate appropriate resources for the upgrading of capacities and capabilities to effectively regulate technology and its products including, but not limited to product testing and labelling.

In response to Intellectual Property Rights (IPR) issues, Republic Act 9168 otherwise known as the **Plant Variety Protection Act (PVPA)** signed into law in June of 2002, protects and secures the exclusive rights of breeders with respect to their new plant varieties by granting them a Certificate of Plant Variety Protection. A certificate is granted if a variety is deemed new, distinct, uniform, and stable.

The Republic Act 9147 otherwise known as the **Wildlife Resource and Conservation Act** enacted in the year 2001 has a specific provision relevant to biosafety and Section 16 in particular, provides provision for biosafety. The law states that all activities relating to genetic engineering and pathogenic organisms in the Philippines, as well as activities requiring the importation, introduction, field release and breeding of organisms that are potentially harmful to man and the environment shall be reviewed in accordance with the biosafety guidelines ensuring public welfare and the protection and conservation of wildlife and their habitats. No specific instrument for biosafety has been referred to, or defined in the Act.

The **Executive Order No. 430 (1990)** established the NCBP and declared a national biosafety policy for the Philippines. The EO mandates the NCBP to perform functions such as, among others:

(1) identifying and evaluating potential hazards involved in genetic engineering experiments, or the introduction of new species and genetically modified organism and recommending measures to minimize risks;

(2) formulating, reviewing, or amending national policies and guidelines on biosafety, such as the safe conduct of work on genetic engineering, pests, and their genetic materials, for the protection of public health, the environment, and personnel; and supervising the implementation thereof;

(3) formulating, reviewing, or amending national policies and guidelines in risk assessment of work in biotechnology, and supervising the implementation thereof;

(4) developing working arrangements with the government quarantine services and institutions in the evaluation, monitoring, and review of project vis-à-vis adherence to national policies and guidelines on biosafety;

(5) assisting in the development of technical expertise, facilities, and other resources for quarantine services and risks assessments; and

(6) recommending the development and promotion of research programs to establish risks assessment protocols and assessment of long-term environmental effects of biological research covered by the guidelines.

National Policies on Biosafety under EO 430

The Executive Order 430 recognises that it is in the best interests of the Philippines to have national policies regulating work on biological measures that are potentially hazardous to crops, livestock, poultry and humans, including aquatic flora and fauna. It further promulgates that:

(1) the Philippines, as a signatory to the Biological Weapons Convention (WC), shall not engage in any activity related to chemical and biological warfare;

(2) the Biosafety Guidelines should apply to all research, production and manufacturing work and/or institutions in the country, whether public or private, national or international engaged in genetic engineering work; and Guideline coverage also includes importation, introduction and/or breeding of plant pests and potentially harmful microorganisms;

(3) any work covered by the Guidelines must be reviewed and approved by the NCBP before its implementation; and for a more efficient and effective system of reviewing work proposals and/or import and introduction of regulated materials, each institution engaged in research, production, manufacturing and/or introduction involving potentially hazardous biological work is required to create its Institutional Biosafety Committee (IBC);

(4) the primary responsibility of enforcing the rules and regulations on biosafety rests on the institution involved and its scientists; and

(5) the monitoring of the work is a responsibility of the institution, however, the monitoring of work dealing with imported or introduced pests should be the responsibility of the quarantine services of the government.

The revised **Philippine Biosafety Guideline (PBG)** issued by the National Committee on Biosafety of the Philippines (NCBP) in 1998 prescribed guidelines on planned release of GMOs and PHES. It covers the intentional release of GMOs and PHES into the Philippine environment and established the criteria for evaluating the planned release into the environment, or field testing, of GMOs and PHES. It specifically excludes from its coverage work performed under contained conditions; accidental release from contained facilities; use of pharmaceuticals, processed food, animal feed, industrial, and other products that are already being regulated by other departments, agencies or instrumentalities of the Philippine government; work involving organisms which result from natural reproduction or the use of traditional breeding practices; and such other activities as the NCBP may in the future declare to be excluded.

The Department of Agriculture's **Administrative Order No. 8 Series of 2002 (AO 8)** prescribes rules and regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology. The AO 8 was issued primarily to supplement the existing guidelines on the importation and release into the environment of the products of modern biotechnology and by institutionalising existing operational arrangements between the Bureau of Plant Industry (BPI) and the NCBP. It also provides regulations that control the release of such products for propagation or for direct use as food or feed, or for processing.

Before any importation or release into the environment of regulated articles, the AO mandates mandatory risk assessment to determine whether a regulated article poses significant risks to human health and the environment. The AO states as its principles (1) that risk assessment needs to be carried out in a scientifically sound and transparent manner based on available scientific and technical information; (2) the concept of substantial equivalence in identifying risks should be adopted; (3) risk

assessment should be carried out on a case-by-case manner and on the basis of transformation event; and (4) according to the principles provided for by the CPB. The AO stipulates however, that the conduct of risk assessment should be in accordance with the policies and guidelines on risks assessment issued by NCBP.

Administrative Order No. 8 specifically outlines the approval process and sets the corresponding policy and requirements for importation for contained use, field testing and release for propagation of regulated articles; and for importation of regulated articles for direct use as food or feed, or for processing. The main regulatory agency in-charge to implement AO 8 is the DA-BPI.

4.2.2 Governance and Regulatory Frameworks

There are four government departments that are involved with the governance and regulatory activities related to biosafety in the Philippines. The Department of Science and Technology (DOST) is the department to which the NCBP is attached as it is the prime research and development institution in the country. The DA on the other hand, is responsible for administering and regulating GMO applications related to crops and animals, although at present they are focused on crops which are handled by the DA-BPI under AO 8 in particular. The DENR has governance and regulatory functions as well in terms of dealing with the potential impact of GMOs and PHES on the environment and biodiversity, and the potential development of GMOs for bioremediation and as biological control agents. However, the DENR has no particular rules and regulations on GMOs yet, and any application that concerns DENR will be handled under the NCBP guidelines. In view of the potential adverse effects of GMOs on human health and for potential application for GMO medicines, the Department of Health (DOH) is the primary body in-charge of handling it, although like the DENR, the DOH has no rules and regulations set in place yet.

<u>The NCBP</u>

The NCBP is the highest regulatory body in the Philippines with respect to the introduction, use and transfer of GMOs and PHES. It is responsible for ensuring that no person or institution, whether public or private, releases any GMOs or PHES into the environment without its prior approval subject to compliance with any rules, regulations, or requirements of other government regulatory agencies. While the NCBP has broad responsibilities, its decisions are considered recommendatory and relies on its member Departments (*i.e.* the DA, DENR and DOH) to approve the recommendations of the committee. Hence, the regulatory functions actually rely on its member regulatory agencies.

The NCBP is a multi-disciplinary, inter-agency, scientific and technical advisory committee tasked with undertaking the study and evaluation of existing laws, policies and guidelines on biotechnology; and recommending measures for its effective utilisation and prevention of possible pernicious effect on the environment. It acts as a technical evaluation body that reviews proposals for biotechnology specifically those applications on the use of GMOs; however it also has jurisdiction on applications concerning potentially harmful exotic species (PHES). The inclusion of PHES broadened the scope of NCBP and as a result more than 95% of the applications filed with the NCBP have nothing to do with GMOs but rather with PHES (Ochave & Estacio 2001).

A recent action of the NCBP was to clarify its understanding of its own mandate. The NCBP viewed that its 'approval' or 'disapproval' of biotechnology applications is restricted to: research and development (*i.e.* laboratory and field tests); technical aspects (whether or not on the basis of existing science safety risks are considered acceptable; and scientific advice (*i.e.* directed to pertinent line agencies to provide them with a basis for acting on proposed applications). The Committee deemed that it reviews proposals for biotechnology applications for the benefit of final approving bodies (e.g. the DA in the case of crop biotechnology); and it communicates directly with proponents for the purpose only of ensuring that it has the best information for a rigorous review of the technical aspects of the safety of biotechnology applications.

The NCBP Structure

The NCBP is composed of ten (10) members including the Department of Science and Technology (DOST) Undersecretary for Research and Development who acts as its Chair. The other members of the Committee include four (4) practising scientists representing a biological scientist, an environmental scientist, a physical scientist, and a social scientist; two (2) respected members of the community; and one (1) representative each from the DA, DENR, and DOH. The NCBP is aided in its functions by these regulatory agencies.

At the core of the structure is the NCBP aided in its functions by the regulatory agencies, the Institutional Biosafety Committees (IBCs) and the Ad Hoc Technical Subcommittees (**Figure 2**).

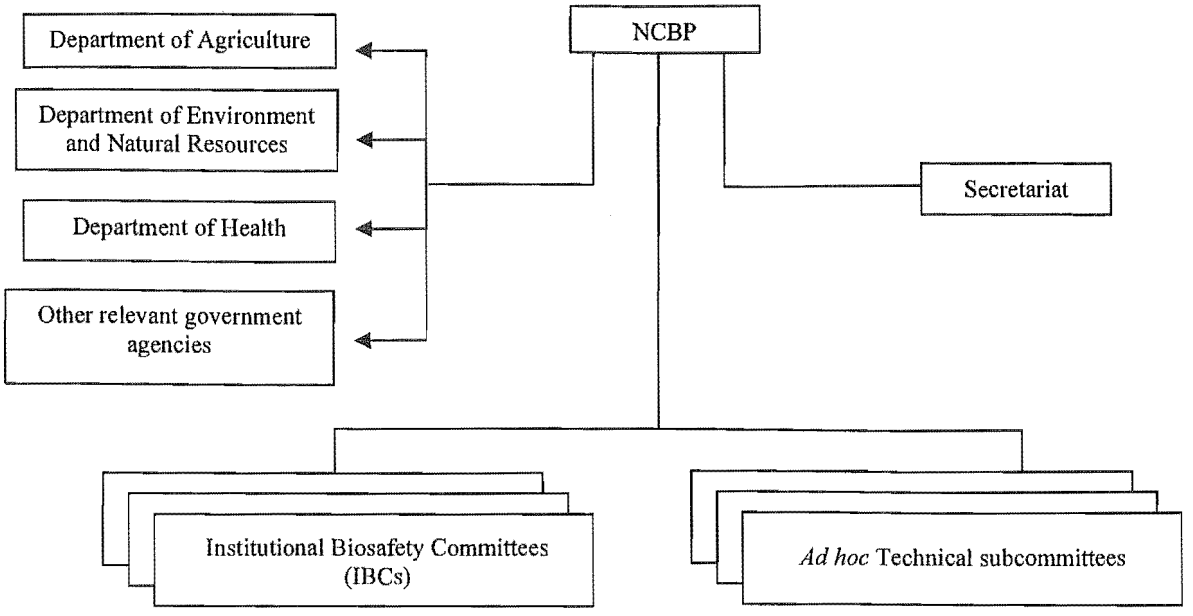

Figure 2. A framework of the way the NCBP coordinates with existing regulatory agencies, IBCs and *Ad hoc* Technical Subcommittees (Source: NCBP 1998).

The term of office of the Chairman of the NCBP is coterminous with his/her appointment as Undersecretary for Research and Development. All members excluding the Chairman serve for a term of three years renewable for another term or more under exceptional circumstances. The four scientist members must have a minimum of seven years of academic and post academic training (degree and/or non-degree) in their respective field. Representatives of the regulatory agencies are designated by the heads of their respective agencies while the rest of the members are appointed by the President of the Philippines.

The Institutional Biosafety Committee (IBC)

Any institution intending to engage in genetic engineering and/or potentially hazardous biological work; or to undertake any planned release of GMOs or PHES into the environment must first set up an IBC. The IBC is responsible for evaluating project proposals involving organisms covered within the Biosafety Guidelines and for recommending such proposals for appropriate action by the NCBP. After a project has been approved, the IBC is responsible for supervising, monitoring and reporting its progress to the NCBP. It is also the IBC's task to ensure that environment and human health are safeguarded in the conduct of any potentially bio-hazardous activities by the institution or by any of its employees or researchers; and that the surrounding communities are well-informed of plans for any planned-release and its concomitant risks.

An IBC is composed of at least five members, three of whom are designated as 'scientist members'; while the other two should be designated as 'community representatives' and must not be affiliated with the institution apart from their affiliation with the IBC. The community representatives must be in the position to represent the interest of the surrounding communities which may be affected by the planned release of GMOs or PHES into the environment.

CHAPTER 5

BIOSECURIY AND BIOSAFETY SYSTEMS, POLICIES AND REGULATIONS IN NEW ZEALAND

This chapter profiles and outlines the existing biosecurity and biosafety policies, laws and regulations in New Zealand. It elucidates the existing mechanisms, and the governance and regulatory frameworks in place in the country noting the interface between the biosecurity and biosafety systems in place.

5.1 Biosecurity Systems, Polices and Regulations

5.1.1 Existing Policies/Laws

This section focuses on the main Acts that have direct relevance to biosecurity. It also looks at the interface of the existing legislations.

The New Zealand **Biosecurity Act** of 1993 was the world's first; a law relating to the exclusion, eradication and effective management of pests and unwanted organisms. The Act covers all organisms (including new organisms) and provides among others, regulation for: importation of risk goods, surveillance and prevention from pest and unwanted organisms, pest management (strategies for both national and regional) and the enforcement and penalties for offences committed against the law. The Act also stipulates the responsibilities, powers and functions of the Minister for Biosecurity and local authorities (*i.e.* regional councils).

Under the Act, no biosecurity clearance is given for any goods unless the inspecting officer is satisfied that the goods are not risk goods, or that they comply with the requirements specified in an import health standards in force for the goods. Risk goods on the other hand, are defined in the Act to mean any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) may: cause unwanted harm to natural and physical resources or human health in New Zealand, or interfere with the diagnosis, management, or treatment, in New Zealand of pests or unwanted organisms. The Biosecurity Act is administered by the Ministry of Agriculture and Forestry.

The **Hazardous Substances and New Organisms (HSNO) Act** enacted in 1996 is relevant to biosecurity in the sense that it regulates the importing, developing or manufacturing of hazardous substances and new organisms. In particular, Section 97A of the HSNO Amendment Act 2003 gave

MAF the responsibility as the enforcement agency to ensure that the provisions of the Act are enforced in respect of new organisms.

The Strategy

The New Zealand **Biosecurity Strategy**, published in August 2003, outlines a comprehensive set of expectations for the future performance of the biosecurity system[25]. The Strategy provides the blueprint for the action and the direction of New Zealand biosecurity. It sets out a vision for all of the different activities in biosecurity. It encompasses all environments (land, freshwater and marine) and both indigenous and valued introduced plants and animals. The overall expectation in the Strategy is that the "biosecurity system is fully integrated, operating efficiently and transparently in an environment of continuous improvement." The strategy has set more than 50 expectations for the future state of the New Zealand biosecurity system. Most of the expectations have a longer term focus, and describe the sort of objectives that should be aimed for, rather than the specific actions that need to be undertaken to achieve those objectives. Three of the main expectations are that:

(1) the biosecurity system will be fully integrated, and operating efficiently and transparently in an environment of continuous improvement;

(2) the system encourages all New Zealanders to participate and support biosecurity; and

(3) there is an annual review with external stakeholders on the performance and development of biosecurity.

The strategy also notes that the biosecurity system must respond to the needs of Māori, both as the Crown's treaty partner and as an emerging economic force. Some of the other key expectations relate to improving institutional arrangements, plugging capability gaps, adopting a consistent approach to funding sources, and improving systems and processes.

5.1.2 Governance and Regulatory Framework

Governance Framework[26]

[25] Overview of Biosecurity. www.biosecurity.govt.nz/about/overview.htm. Date retrieved: 03 October 2005.
[26] This section was informed by referring closely to the June 2005 Memorandum of Understanding between MAF, DOC, MFish and MOH.

The Ministry of Agriculture and Forestry (MAF) has been given accountability for the end-to-end management of the biosecurity system (Sutton 2003). This means that MAF is accountable for biosecurity system oversight encompassing both those that MAF controls and those over which MAF has no direct control. The Memorandum of Understanding (2005) specified the elements of system oversight which include: facilitating a shared sense of strategic direction; providing commentary and advice to the Minister for Biosecurity; facilitating cooperation and coordination; national leadership and coordination, including that of pest management; and gathering information and reporting.

Cabinet noted that this would mean that once the new arrangements were fully implemented the chief executive of MAF would be accountable to the Minister for Biosecurity for strategic, regulatory and service delivery functions, from pre-border through to pest management, that contribute to health, environment, economic, and socio-cultural outcomes.

The Minister for Biosecurity and Associate Minister for Biosecurity hold the overall accountability for New Zealand' biosecurity activities and decisions (MOU 2005). Of political significance, the incumbent[27] Minister for Biosecurity is also the Minister for Agriculture, Minister for Trade Negotiations, and Associate Minister for Rural Affairs. The minister was also the former Chair of Primary Production and Rural Services Caucus Committee and of the Finance Select Committee. Currently, the Minister is also representing New Zealand on the World Trade Organisation (WTO) and responsible for promoting New Zealand's Trade Policy.

In performing its functions and making decisions, the Biosecurity Minister is informed through four governing and advisory bodies, namely:

(1) the Ministerial Committee for Biosecurity,

(2) Biosecurity Ministerial Advisory Committee (BMAC),

(3) Biosecurity Chief Executives Forum (CEs Forum), and

(4) the Biosecurity Central/Regional Government Forum (BCR Forum).

The Ministerial Committee for Biosecurity comprises the Ministers of Biosecurity (as the lead Minister), Agriculture, Conservation, Fisheries, Health and the Associate Minister for Biosecurity. The Committee is primarily convened when there are biosecurity issues of major cross-sectoral importance. It is further tasked with overseeing plans and review systems performance, among others (MOU 2005).

[27] At the time of writing, New Zealand was having its MMP election.

The BMAC on the other hand is a multi-stakeholder advisory committee formed to provide independent advice on the performance of the overall system and monitor the implementation of the New Zealand Biosecurity Strategy. The BMAC replaced the disestablished Biosecurity Council. While MAF has overall responsibility for the performance of the overall biosecurity system, the Chief Executives Forum has been created to ensure clarity of roles, accountabilities and responsibilities among the agencies concerned. Currently, the Forum is composed of the Chief Executives of MAF, DOC, Mfish and MOH. In terms of providing an interface between central and regional government, the Biosecurity Central/Regional Forum was created to improve coordination and collaboration across central and regional government biosecurity agencies. As providers of pest management services, regional councils are recognised as critical components of the end-to-end management of biosecurity[28].

Strategic level

The Biosecurity Strategy Unit (BSU) acts as Secretariat for the four governance/advisory bodies. The BSU operates as an independent group reporting directly to the Director General of MAF and focuses on providing strategic advice on the biosecurity system as a whole[26]. It is responsible for developing longer-term strategic directions for the biosecurity function, and evaluation of performance in view of relevant biosecurity responsibilities and activities across the systems.

Operational level

Established in November 2004, Biosecurity New Zealand (BNZ) is the lead agency in New Zealand's biosecurity system and replaces the MAF's Biosecurity Authority. It is tasked with a 'whole of system' leadership role, encompassing economic, environmental, social and cultural outcomes[29]. The BNZ is the division of MAF that has the lead role in preventing the importation of unwanted pests and diseases, and for controlling, managing or eradicating them should they arrive. A new structure for BNZ was also created; it consists of six structural units reporting to the Assistant Director-General (ADG) for Biosecurity[30] i.e. pre-clearance, post-clearance, policy and business, animal welfare, compliance and enforcement, and incursion investigation and reference laboratories. At the operational level, it follows a point of intervention approach at the pre-clearance and post-clearance units. At the pre-clearance directorate, it manages biosecurity risks before they enter the border or at the border. It consists of four groups *i.e.* risks analysis, biosecurity standards, monitoring, and exports. On the other hand, the post-clearance directorate manages 'residual' biosecurity risks, i.e. risks that cannot be managed by pre-clearance activities or that remain after pre-clearance conditions have been met, or

[28] Biosecurity Strategy Unit. www.maf.govt.nz/biosecurity-strategic-unit/. Date retrieved: 03 August 2005.
[29] Overview of Biosecurity New Zealand. www.biosecurity.govt.nz/about/overview.htm. Date retrieved: 14 July 2005
[30] Source: Introducing Biosecurity New Zealand, a pamphlet provided during the 2nd Biosecurity Summit in November 2004 held in Auckland.

where risk is already present within New Zealand. It is divided into surveillance and incursion response, and pest management groups.

5.2 Biosafety Systems, Polices and Regulations

5.2.1 Existing Policies/Laws

The **HNSO Act 1996** sets the environmental and health and safety law in New Zealand. The purpose of the Act is to protect the environment, health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms. The Act provides a process for assessing the risks posed by hazardous substances and new organisms and for setting national controls to manage their environmental effects and risks. The Act created the Environmental Risks Management Authority (ERMA) to be the prime body responsible for making decisions about importing, developing or manufacturing hazardous substances and new organisms. The Act established a consistent process for assessing the risks posed by hazardous substances and new organisms and for setting national controls to manage their effects and risks. Enforcement of the Act for new organisms started on 29 July 1998 and for hazardous substances on 2 July 2001. New organisms under the HSNO Act can be any organism belonging to the following:

(a) a species that was not present in New Zealand before 29 July 1998;

(b) a species that has a containment approval under the HSNO Act;

(c) a genetically modified organism (GMO);

(d) a subspecies, infra-subspecies, variety, strain or cultivar that has been determined (by regulation) as a risk species and that was not present in New Zealand before 29 July 1998; or

(e) a species, subspecies, infra-subspecies, variety, strain or cultivar that has been eradicated from New Zealand.

<u>The HSNO Amendments Act</u>

All genetically modified organisms are classified as "new organisms' under the HSNO Act. Consequently, ERMA has direct control over GMOs and serves as the regulatory body to cover biosafety issues concerning GMOs. The legal definition of a GMO in the HSNO Act states that "a

GMO means...any organism in which any of the genes or genetic material – (a) have been modified by *in vitro* techniques; or (b) are inherited, or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques."

In 2002, HSNO Act was amended to tackle particularly the outstanding issues related to GMOs. The HNSO Amendment Act 2002 required the ERMA (the Authority) to take into consideration "additional matters when considering applications in relation to GMOs, and if it approves the applications, to include particular controls for field tests and certain developments[31]." The 2002 amendment also imposed a restricted period[32] of two years which started on 29 October 2001 and ended on 29 October 2003 for approving certain GMO related applications. During this period the Authority was mandated to cease consideration or approval of the following applications:

(a) any application to import a new organism for release; and

(b) any application to release a new organism from containment.

Again, in October 2003, the Parliament made amendments to the HSNO Act. The HNSO Amendment Act 2003 officially lifted the moratorium and led to key changes in the legislation. Among others, changes include:

(1) *Streamlined low-risk approvals*. Changes were made to ease the regulatory burden on scientific researchers working on GMOs in containment. For example, the law now allows a single approval of a variety of genetic modifications on a project basis, rather than requiring a separate process for each organism and transformation involved;

(2) *Streamlined procedures for assessment and approval of animal or human medicines that are or contain low risk new organisms, including approvals to deal with emergency situations*;

(3) *Extended grounds on which the Minister may call in applications to include significant cultural, ethical, and spiritual effects*;

(4) *Creation of the new category of "conditional release."* The new category will allow ERMA to approve the release of new organisms with conditions imposed to protect the environment and crop co-existence;

[31] Certain developments include a medicine or new medicine; veterinary medicine used for therapeutic or prophylactic purposes; and those that are subject of a clinical trial approved by the Director General of Health.
[32] Others referred to it as "moratorium"

(5) *Specification of one agency (the Ministry of Agriculture and Forestry) to be responsible for all enforcement of HSNO's provisions regarding new organisms.*

(6) *Changes to better incorporate Māori viewpoints.* The amendments created a new advisory board to work with ERMA on Māori issues, and made provisions for allowing expertise in Māori issues to serve as a basis for appointment to the Authority; and

(7) *Liability.* The amendments provided penalties and civil liability for breaches of the Act.

5.2.2 Governance and Regulatory Framework

The Minister/Ministry for the Environment

The Minister for the Environment appoints members of the Authority of ERMA. The Minister also issues policy direction in view of regulating hazardous substances and new organisms. Of a particular power given to the Minister is the term "Minister's Call-in". This means "the Minister can call in and decide on an application that the Minister considers to be of national or international significance (ERMA 2001)." The Ministry for the Environment advises the government of policies, laws, regulations, and other means of improving environmental management in New Zealand. The Ministry carries out many of the statutory functions of the Minister for the Environment. It monitors the work of ERMA on behalf of the Minister; focuses on providing advice on the administration of hazardous substances and new organisms; and works towards development of relevant policies and regulations. The significant areas of policy for which the Ministry is responsible are: management of natural resources; sustainable land management; air and water quality; management of hazardous substances, waste and contaminated sites; protection of the ozone layer; and responding to the threat of climate change. **Figure 3** outlines the structural framework of the ERMA in terms of regulating new organisms.

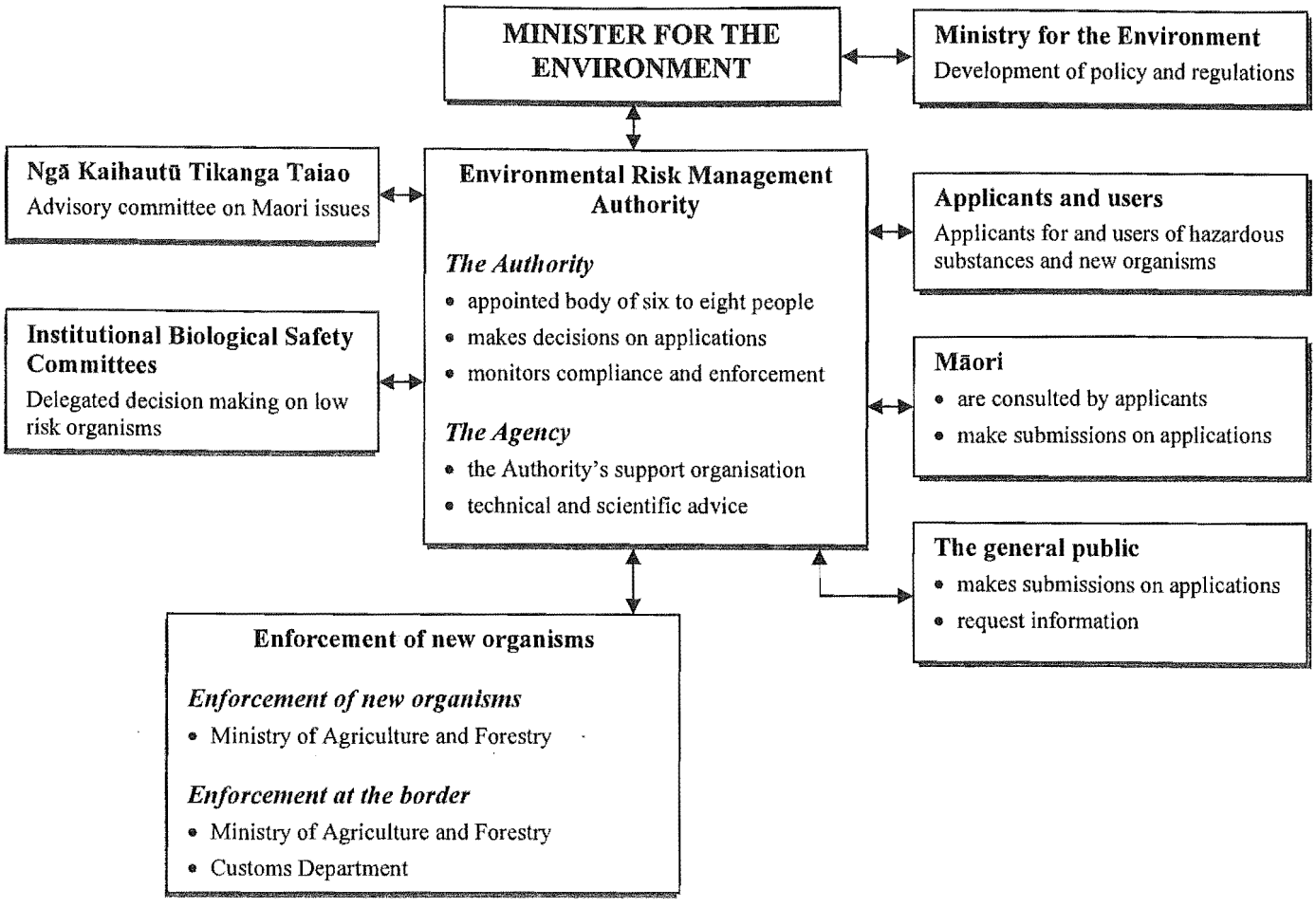

Figure 3. Structural framework of the Environmental Risk Management Authority in view of regulating new organisms (Source: ERMA 2005).

The Authority

ERMA New Zealand is a crown entity and acts as a quasi-judicial body. It is comprised of three formal elements – the Authority, the Agency, and Ngā Kaihautū Tikanga Taiao.[33] The Authority is composed of eight people appointed by the Minister for the Environment and is responsible for exercising statutory functions and acting as the governing body of ERMA New Zealand. They have two main roles, *i.e.* (1) they are the decision makers – they are the people who make decisions about whether or not hazardous substances or new organisms can be imported, developed or manufactured in New Zealand; and (2) they also monitor compliance and enforcement in view of the HSNO Act. The Authority has a governance role over the Agency. They serve as boards of directors overseeing the operational, financial and organisational status of the Agency. In making decisions on approvals on hazardous substances and new organisms, the Authority "must take into account specific matters

[33] ERMA Statement of Intent 2004/2005.

including the economic, social and cultural well-being of all people and communities in New Zealand and the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga (ERMA 2001)." This is being facilitated by close coordination between the Authority and Ngā Kaihautū Tikanga Taiao. Ngā Kaihautū is a statutory Māori Advisory Committee established under Part 4A of the HSNO Act, and is required to provide advice and assistance, as sought by the Authority, on matters relating to policy process and applications (ERMA 2004). The Authority also established an ethics and advisory panel to assist in its consideration of ethical and spiritual matters in decision-making (**Figure 3**).

The Agency

The Agency serves as the Authority's support organisation. It provides technical and scientific advice to the Authority in making its decisions. It is headed by a Chief Executive with six group managers and manned by around 100 staff with relevant technical expertise for evaluating and processing applications, administering the public consultation process and acting as the Authority's public interface (Ministry for the Environment 2001). In simple terms, the Agency receives the application, evaluates it, ensures that all information relevant to the application are obtained, conducts risk assessment and eventually present the risk assessment to the Authority for appropriate actions (Harrison *pers. comm.*). Another key role of the Agency is to screen applications and provide advice and information to potential applicants. The Agency is also in-charge of coordinating with the Institutional Biological Safety Committees (IBSCs), enforcement agencies, members of the general public and Māori.

The IBSCs

Decisions on the development of low-risk GMOs and their importation to secure containment can be done through a rapid assessment process (ERMA 2003). The prerogative to make these decisions may be delegated by the Authority to IBSCs which are based in academic and research institutions (ERMA 2003). IBSCs usually consist of members of the institution where the research would be undertaken and members of the community in which the institution is situated, including a Māori representative (Ministry for the Environment 2004). The IBSCs are expected to keep detailed records and report their actions to the Agency who oversee their work. They are regularly checked, audited and guided by staff from the Agency to ensure that rules and correct procedures are followed. In terms of compliance, MAF visits and checks the laboratories where low-risk research is carried out in containment. According to Harrison (*pers. comm.*) about 80% of decisions are made at the low-risk level.

CHAPTER 6

BIOSECURITY AND BIOSAFETY ISSUES AND CONCERNS IN THE PHILIPPINES

This chapter presents and discusses the intertwining issues, concerns and challenges to biosecurity and biosafety in the Philippines. This chapter has two sections. The first focuses on the biosecurity issues and concerns and the second delves into the biosafety issues and concerns.

6.1 Biosecurity Issues and Concerns

6.1.1 Understanding the Term Biosecurity

One of the issues in biosecurity is that it is a relatively new term especially for developing countries (FAO 2004). In the Philippines, this study confirmed that the term biosecurity is still unfamiliar and is not adopted widely. Evidence from interviews conducted by the researcher and documents retrieved for the purpose of this study reveal that its scope is not yet fully understood. The term biosecurity in the Philippines is also used interchangeably with biosafety. Officials interviewed by the researcher admitted that perhaps even the political leadership is unaware of the term biosecurity. There are only two or three scientists who understand the concept of biosecurity according to the FAO and New Zealand's definition, and one of them however, considers biosecurity to be directly relevant to food security[34]. There is clear confusion about the term for many and the following responses from top government officials and a scientist further confirm the unfamiliarity of the concept:

> *The term biosecurity is not even yet adopted widely; people probably do not understand yet what its scope is and biosafety is sometimes confused with biosecurity or used interchangeably with biosecurity but, well for those who are aware of the distinction between the two it's not good practice to mix them up.*

> *I'm not too familiar with it. Yeah, what is it?*

> *I'm not sure whether even the political leadership is aware of the concept of biosecurity.*

[34] Dr. William Padolina, Deputy Director General for Partnership of the International Rice Research Institute (IRRI), presented a topic on: *Biosecurity and Food Security* at SEARCA on 29 January 2004. A PowerPoint presentation for the said topic was obtained by the Researcher.

Interestingly, others have their own personal understanding and definition of the concept. One scientist opined that:

> *Biosecurity is more about preserving biodiversity against commercialisation by external entities and influences.*

An environmental scientist on the other hand, put forward the concept of environmental security:

> *I haven't encountered the term biosecurity but what we have here as a matter of strategy is the term environmental security; which is ensuring that human life and property are within a controllable level and that are otherwise generated from the environment. The second aspect of that is that human activities do not harm the environment, or the harm to the environment is within controllable levels.*

The definition provided by the scientists may not be the mainstream definition of the term biosecurity, but it categorically shows that the concept of protection of biodiversity and the environment are being directly related to the term biosecurity. The next section embarks on discovering how biosecurity is perceived in view of the associated risks attached to it.

Biosecurity as a matter of terminology may be unfamiliar in the Philippines, however, if it is broken down into its associated risks (regarded as biosecurity risks) such as: invasive alien species, animal and plant pests, and zoonotic diseases, a better understanding of it emerges. Based on the interviews conducted by the researcher, and from the public documents and news articles collated for this research, the threats of Avian influenza, severe acute respiratory syndrome (SARS), red tides, formalin contaminated vegetables, invasive alien species, high profile plant pests such as golden kuhol and water hyacinth, and animal diseases such as foot and mouth disease (FMD) and Bovine Spongiform Encephalopathy (BSE), among others were particularly recognised as critical problems in the Philippines. The risks from these threats are therefore considered high and are perceived to have a great impact on food security, the health, environment and the economy in the country. A former top government official highlighted these concerns:

> *Biosecurity has always been one of my concerns because even before there were already reports of Avian Flu in Hong Kong and of course we had occasional incidents here in the Philippines of formalin contaminated vegetables, but we also have red tides here, that are seasonal in occurrence, plus of course other packaging problems of foods that are not hygienically prepared, so it's not just food or materials coming from outside*

but also internally. The practice and standards of food safety are not complied with. I know there are regulations but the compliance is very poor.

6.1.2 Invasive Alien Species

Another issue related to biosecurity is the rising problem with invasive alien species (IAS). In the Philippines, there appears to be a growing awareness and recognition of the threat posed by IAS. One scientist interviewed by the researcher confirmed that there are already known instances of intentional introductions of new species that have not resulted in economic benefit (which is primarily the reason for such introduction), but have caused adverse environmental and economic consequences in the Philippines instead. The scientist recounted the dismay caused by the intentional introduction of the golden apple snail (*Pomacea caniculata*), locally known as golden kuhol; which was purposely imported as a source of protein to prevent malnutrition, and as an aquarium novelty but it unexpectedly became a major pest to newly planted rice seedlings and displaced the native Philippine snail (*Pila luzonica*). Concerns were expressed however that the issue of IAS is not given enough attention and that the government and the public are too focused on the issue of GMOs. One environmental lawyer and a scientist commented that IAS are a much bigger threat to the country:

To me invasive alien species is a much bigger issue that the Philippines should be tackling compared with the issue of GMOs. The problem is it is given less attention, less funding but it is definitely a much bigger problem.

I would say exotics or invasive alien species are bigger threats than GMOs. Why? They are already here within the country before we react, as somebody has already introduced them into the environment; at least with GMOs we assess them first before we allow them to enter the country. So at least we are able to reduce the risks in the case of GMOs.

The researcher found out that the dilemma over the issue of IAS was evident even during the development of the NBF. Based on the transcripts of the actual proceedings of an expert consultation conducted for the development of the NBF in 2003, it was revealed that the participants were concerned about whether to place IAS within the scope of the proposed NBF or put it in a separate framework. There were those who argued that dealing with two different organisms (a GMO and an invasive species) in one framework would run the risk of confusing the public by suggesting some comparability between the two. During the discussion about the NCC, it was noted that the process provided for under the proposed NBF is primarily for addressing GMOs and that it might be potentially difficult to apply the same process to the issues of exotic species and IAS. However, while

most were not convinced that IAS should fall under the scope of the NBF there is no alternative framework yet where it can be covered. One government official voiced this uncertainty:

> *Of course there's the issue of invasive species but we don't know whether it should fall under the proposed national biosafety framework or whether they should be covered by a different policy paper altogether.*

In the end however, the NCC decided to retain the inclusion of exotic species and invasive alien species with a caveat in paragraph 2 of Section 3.1 of the proposed NBF stating:

> *The NCBP and concerned departments and agencies may apply, when allowed by law, the principles, mechanisms and processes developed and implemented under the NBF to similar problems such as addressing the issue of exotic species and invasive alien species. Where appropriate, they may adopt the administrative and decision-making systems established in this Framework. (Draft Executive Order 2004)*

6.1.3 Pest Management

In the Philippines, the current trend for pest management is a knowledge-driven, knowledge-based, location specific understanding of ecology and ecosystems; however, the country is lacking basic research on pest and disease ecology, and as a result farmers decided to respond according to their own best understanding of the situation and through Farmer Field School (FFS) also known as community Integrated Pest Management (IPM). The underlying concept behind FFS was really about reducing pesticide use since it is the most apparent problem, but when it comes to actual national pest control strategy there is no national effort at present. The researcher discovered that in some cases the approach was very *"ad hoc" i.e.* forming an *ad hoc* committee or an *ad hoc* task force to address problem of a particular pest (Velasco *pers. comm.*). In terms of pest eradication, the Philippines has no authentic experience or program to eradicate pests. The main attempt at eradication was with the mango pulp weevil in Palawan but this did not materialise due to logistical constraints and the difficulty of convincing farmers to cut down their trees, or not allowing them to bear fruit for three years. Moreover, at the time of this study, the researcher could not locate an economic study that estimated the impacts made by a pest on the country's economy or how it affected the farmers themselves. A professor and one government scientist interviewed by the researcher were uncertain of any study conducted on that matter:

> *I am not sure if there has been a formal economic impact study (or one yet to be done) in the Philippines. Usually we do not do that because it is quite expensive; the idea is to*

use the money on other activities that would produce positive gains rather than on retrospective studies.

There's no economic impact study that I can remember that measured the impact made by pests and diseases on the economy of the country and how they affected the farmers, for instance.

Considering the above situation, it could be assumed that the lack of support for a more stable (instead of an *ad hoc*) pest management strategy for instance was due to the lack of realisation and recognition of the economic and environmental impacts that pests had on to the country.

6.1.4 The need for a Biosecurity System

Based on the documents collated by the researcher, the need for a biosecurity framework first surfaced during an expert consultation workshop for the proposed NBF. However, since the focus was on biosafety, biosecurity did not gain prominence and it was suggested that it be looked at in another forum. There were strong views however, which invoked the need to have a biosecurity system in place in the country. As one former government scientist and administrator pointed out:

I think we need biosecurity in the Philippines as part of our governance because of the liberalisation of trade when food materials and other materials that impact on human health and the environment come in. We need to have a biosecurity policy so that we can invoke that when we open our markets...the SPS allows for countries to refuse entry to products that they deem harmful to their environment and to human health. But if we don't have a system in place, even if that were allowed, we will not be able to undertake regulatory activities.

The link of biosecurity to a healthy nation and an efficient workforce was also cited. According to one scientist there is a direct connection between biosecurity and a strong populace:

I hope they (the politicians) will pick it up (the issue of biosecurity) because in the long term it will affect the efficiency of the nation. Imagine if you are eating, and you are already malnourished, you'd be eating food that is contaminated, so you are already subjecting a good portion of your population to jeopardy. Now, will they be efficient? Probably not, because they will be affected by these contaminants. Maybe their thought processes will not work, they might be lethargic with no energy. So how can you push or expect them to work efficiently? On that score, I think the politicians, the Congress and

the Executives should really pay attention to this, and it is really because we are opening our markets. even from our Asian neighbours.

Another scientist further emphasized the need for a regulatory system and the necessary infrastructure that comes with it. It was underscored in the scientist's statement that biosecurity should be a national decision and that a regulatory system should be put in place:

Now if you don't have a regulatory system to monitor them whatever way, either at random or at a single gate I think you subject the population to a very high degree of peril. So, I hope that our politicians will realise it is necessary to put these systems in place. It's really putting in an infrastructure of laboratories and institutions that can perform the monitoring, and for our Port authorities to be educated also on how to visually detect possible contamination.

Based on the above statements, the need for a biosecurity system in the Philippines is an issue that cannot be overlooked. The apparent consequence of not having a regulatory regime to address the matter will be further substantiated in the succeeding sections below.

6.1.5 Border and Quarantine

One of the issues related to biosecurity that appeared during the conducting of this study was the situation on the Philippine border. It was admitted that the system at the border is very porous. As one top government official explained:

Our system at the border is very porous, it's very porous. We have a coast line the length of which is twice that of the United States because each island is to be measured, and surrounded by large bodies of water. We also have a navy that is ill-equipped and a coast guard that is also ill-equipped, therefore, we have very porous borders and products which are unmonitored or smuggled enter. This is a matter of great concern).

There is also concern that the current quarantine system is very weak. According to one plant scientist, the Philippine quarantine system lacks technical expertise in terms of carrying out Pest Risk Analysis (PRA) as part of the International Standards for Phytosanitary Measures (ISPM) 2 & 11, issued by FAO-IPPC in 1996 and 2004, respectively. The lack of sufficient funds to conduct a good PRA and to put up quarantine infrastructure and facilities were the other underlying reasons that contributed to a weak quarantine system in the country. To produce much needed funding, quite recently the Philippines Department of Agriculture and the Department of Trade and Industry sought

US support for a US$ 10 million grant for the procurement of irradiation equipment that would help facilitate the entry of Philippine mangoes to the US. The irradiation machine uses ionizing radiation to eliminate pests and bacteria from food intended for exports to meet the sanitary and phytosanitary requirements of importers (Campos 2005). These concerns can be viewed as significant if we look at the number of seaports, for instance in the whole Philippine archipelago which are used for handling almost 98% of the total imports and exports. Based on a public document retrieved by the researcher, there are 42 ports considered crucial to the Philippines economic development which are to be equipped with infrastructure and landslide equipment to enhance their competitive advantage. There are also over 1000 small, domestic ports within the whole archipelago. The situation of having a weak infrastructure and a lack of technological underpinning is stressed by one government scientist:

> *A big portion of biosecurity is the technological underpinning; contamination can only be detected technically, we can not just say it is contaminated. For instance, a lot of the claims made to establish the presence or absence of hazardous substances have to be scientifically backed up and they must be backed up by methods that are universally acceptable, and that's where we are weak in this country.*

There was one notable case however where the quarantine system was quite stringent. In the small island of Guimaras (which was declared a Special Quarantine Zone), quarantine measures are quite high in order to keep the island free of high profile pests such as the mango pulp weevil and the mango seed weevil. The underlying reason was to satisfy strict requirements placed by the US on Philippine mango exports which currently only come from the Guimaras Island. Its direct relationship with trade will be presented and discussed in the succeeding section.

6.1.6 Biosecurity and International Trade

This study found that there are several trade related issues that can be connected with the broader issue of biosecurity[35] in the Philippines. One government official commented that the weak science infrastructure in the Philippines, was used by importing countries to put trade restrictions on some Philippine exports:

> *The products that we export, because of the weak science infrastructures here are always subject to the what we may call restrictions of the importing country, and the restrictions are based on their own analysis. And so we do not have the means to*

[35] Since the term biosecurity is not being used in the Philippines (yet), the use of biosecurity in the Philippines in this thesis refers to the more traditional approach to pests and diseases and quarantine mechanisms in the country.

counter them because we have nothing to show that their analysis is not true; we have nothing to show that is our analysis.

This predicament can be best described by providing a few examples such as the case of mango exports to the US. It took 14 years for the Philippines to persuade the US that the small central Philippine island of Guimaras was free of a winged brown pest called the mango pulp weevil and to permit mangoes from Guimaras to enter the US (Cohen 2004). Another example was the trade dispute over Philippine pineapple and banana exports to Australia. In 2002, the Philippines was protesting at the World Trade Organisation (WTO) against non-tariff barriers that Australia imposed on Philippine fresh pineapples. Biosecurity Australia has allowed the entry of Philippine pineapples and mangoes under strict pre-conditions, but banned the imports of Philippine bananas that year (Cabacungan 2002). These impacts on trade have been recognised even at the top level of government. A former Cabinet Secretary interviewed by the researcher for this study underscored the importance of having a good biosecurity system to be able to trade in an equal playing field:

Biosecurity should be two-way the way I look at it. From a developing country's point of view it's two ways and maybe even from other countries' points of view, because a good biosecurity system can make sure your products comply with international standards. Also entering and outgoing products comply with international standards. And you have your own information systems that would generate. And so, in effect you are able to conduct the trade on a level playing field.

6.1.7 Biosecurity as strategically important as national security

The Philippines arguably has not come to the point of discussing more deeply the holistic relationship between biosecurity and national security, although if a particular pest ravaged crops or livestock, or if a particular epidemic of a disease of animals, or from animals-to-humans broke out as in the case of the Avian Influenza, it would be considered a national concern. For Avian Influenza for instance it would be a joint effort between the DOH and the DA and possibly the DENR. The National Disaster Coordinating Council (NDCC) would also be part of it should such a problem turn into a disaster for the country. On the other hand, a former government official opined that the Philippines do not consider biosecurity as national security matter at this stage but are more concerned with the bigger issue of environmental security. The DENR was invited to sit in Cabinet Cluster E which is the National Security Cluster for national security issues that concern the environment. One example of an environmental issue was the dispute between the Philippines and its Asian neighbours (including China) over control of the resource rich island of the Spratlys. It was stressed by the official that what appeared to be a military activity was prompted by deep environmental concerns:

Well it was considered like that for a long time by the Cabinet under President Fidel Ramos, that's why we in the Environment Department were sitting in Cabinet Cluster E, which is the national security cluster. We were not a regular member at that time, but from time to time we were invited to sit in that cluster precisely because many of our national security concerns involve interest in the environment such as the Spratlys. During that time we were very much involved in defining what would be the possible strategy for the Philippines campaign to contain the Spratlys problem... What appears to be a military activity is actually prompted by very deep environmental issues.

Consequently, based on the above statements, it can be argued that biosecurity is not seen or valued yet as a broader environmental concern that should be tackled within the context of bigger environmental security issues in the country.

6.1.8 Biosecurity Encompassing Biosafety

In the case of the Philippines, those who understand the broader concept of biosecurity concurred that to a degree biosecurity should encompass biosafety matters. A government scientist used the example from another country to reinforce such a claim:

Take for instance the Bt Corn in South America... farmers have gone to the extent of stealing seeds, so there is an illegal trade of seeds now in South America. It's a question of monitoring and that's part of biosecurity. That's why I think biosecurity should encompass biosafety in some ways.

One official however, stepped into the discourse and suggested that biosafety should be encompassed not by biosecurity but within the context of environmental security:

To me biosafety should be encompassed by environmental security. The rationale for biosafety should be that one must pursue higher environmental security objectives.

As noted in the earlier section of this Chapter, there is a tendency for cross-cutting issues like biosecurity and biosafety to be engulfed within the broader concept of environmental security. The researcher however, did not descend to a deeper level of research on the concept of environmental security due to limited and restricted access to information, but it would be worthwhile to explore this topic as a separate study.

6.2 Biosafety Issues and Concerns

6.2.1 The Biosafety System in Place

This study found that many believe that the biosafety system in the Philippines is working properly and is considered to be one of the strictest biosafety regimes, at least in the ASEAN region. Given that it is the scientists themselves who initiated the move to have biosafety regulations put in place, justifies the stringent measures that were formed. Hence, the regulations in place for biosafety are fundamentally scientific in orientation. As one environmental lawyer put it:

> *Any person you ask will tell you we have the strictest biosafety regime, outside probably of developed countries. We can ask some of my NGO friends and etc... we have the strictest in terms of the law and in terms of the regulations.*

Others agreed that the biosafety system is functional and run by a balanced group of competent people. They are of course referring to the NCBP as the main regulatory body in charge of biosafety. However, there was general acceptance that the NCBP is undermanned and with a very small Secretariat that does not cope with the number of biosafety related applications each year. Another issue is that most of the members of the NCBP have full time work obligations in various public, private and community institutions or organisations. The normal regular meeting of the members of the NCBP takes place only once a month; though in exceptional circumstances it may be twice a month, especially when there are issues that need immediate attention, and/or decisions. In a more detailed picture on how the system works within the NCBP, a former top government official recounted:

> *I think the biosafety system we now have in place is good and functional but it is under-manned. It does not have a full Secretariat; they only have 1 or 2 people working as Secretariat while they receive 5 or 6, or even up to 10 applications a month. So, the processing is a little delayed, but it is composed of very competent people, I think, people who are good. It's a balanced group: there's a community representative there, a NGO representative and a social scientist as well; and it's I think is functional.*

In the case of DA-BPI which is now regulating all applications for field testing, commercial propagation and importation of plant and plant products derived from the process of modern biotechnology (hence a biosafety matter), there is an intensive capacity building programme that is being implemented within the Department and its Bureaus to make sure that the regulators can cope with the technical and administrative demand of the task. Holistically however, there is a consensus

that "the system must be strengthened, including the capabilities of the different regulatory and implementing agencies, the research institutions, and civil society organisations" (Halos *et al.* 2004: 86). Likewise, many also recognised the complexity of the biosafety issue and others stressed the importance of an NBF for the Philippines.

The Proposed National Biosafety Framework of the Philippines

Based on the archives collated, and from a final workshop attended by the researcher (during fieldwork in the Philippines) on the development of the NBF, it is apparent that the proposed NBF was crafted through mutli-sectoral and multi-stakeholder processes. It went through a series of drafts, each draft being revised based on inputs from multi-stakeholder consultations conducted. One of the issues that was raised by the researcher to a member of the NCC was the potential conflict of the proposed NBF with the existing policies, guidelines and regulations. The NCC member however, pointed out that there was no conflict because the NBF itself is a process-purpose framework rather than a specification-purpose framework. This means that the framework has not specified what to do, but rather focuses on the range of possibilities for action. The exact quote from the NCC member is presented below:

> *I think the NBF will have no conflict with existing policies, guidelines and regulations. In fact it recognises process. There are so many things we don't know yet; and so many things that will still happen in the future. So it has not specified: this is what we do, this is what you do, these are the whole range of possibilities. For example the ethical assessment or, the socio-economic assessment we do not have standards for them yet. That's why, in the NBF standards can be developed... So it's an evolving, it's a creative and a process – purpose framework... rather than a specification – purpose framework.*

There were non-technical issues and concerns however, that surfaced during the process of developing the NBF. One in particular looked at how the financial assistance for the development of the NBF from the UNEP-GEF was used. There was a notion that the funds could have been used in capacity building and an information and education campaign straight away, instead of the UNEP-GEF releasing them in a piecemeal basis, *i.e.* first phase-development of the NBF project; second phase-capacity building. One environmental lawyer and one social scientist commented:

> *That funding from UNEP, to be quite blunt about it is basically a funding in search of a project.*

If you ask me, that money from UNEP which was used to finance the development of that draft NBF could have been spent in a better way, like building the capacity, or information and education campaigns. You look at the draft NBF, you look what the results are and you would say that what they came up with is essentially what we have now.

Interestingly, the researcher found out from one of the NCC members that the second phase of funding for capacity building will only be released by the UNEP-GEF if the Philippines government becomes a Party to the Cartagena Protocol on Biosafety, *i.e.* when it finally ratifies the Protocol. However, in the technical briefing attended by the researcher where chiefs of staff of the Philippine Senate Committees on the Environment were briefed on the issue, it was evident that the there were polarity and contrasting views on the topic. Apparently, most of the technical staff of the Senators, as well as the Senators themselves (the staff are the ones keeping the Senators informed) were not fully aware of the issues pertaining to biosafety and the Cartagena Protocol. In hindsight, the policy makers and/or their duly authorised representatives could have been part of the consultation process during the development of the NBF so that they had a full grasp of the issue even before deliberations commenced for the ratification of the NBF. Based on the correspondence received by the researcher from one of the National Executing Agency officials of the NBF Project, the ratification of the Cartagena Protocol by the Philippine Senate may take a while, and the first hearing was scheduled for September 2005.

Strengthening the functions of the NCBP became one of the major issues in contention during the development process of, and decision-making stage for the NBF. For instance, a government official stated:

The issue in the NBF is they want to expand the functions of the NCBP; that's not a bad idea but the NCBP having a bigger function will mean higher expectations... but your enabling resource support is not enough. My worry is it might get worse instead.

The NCBP members themselves did not like the idea. They were opposed to the notion of creating a supra NCBP whilst having the nuance of no certainty in funding to support its operation:

You know the problem with the initial draft that they made is they want to create a supra NCBP where you have so many members, you know, and without providing any funding. If you are going to create a supra agency that means additional budget, additional people, right now people are already coordinating with each other, people are working together through NCBP and not even through NCBP, even between Department to

Department like DENR and DA. So why do you need a supra agency for, what do you need it for?

In the draft NBF we get a bigger role and we are opposed to that.

What do they mean by a supra NCBP? Sections 4.1 and 4.2 of the Draft EO provide the proposed new mandate and composition[36] of the NCBP. In particular Section 4.1 states:

> *The NCBP shall be the lead body to coordinate and harmonize inter-agency and multi-sector efforts to develop biosafety policies in the country (where such are not already stipulated by law) and set scientific, technical and procedural standards on actions by agencies and other sectors to promote biosafety in the Philippines; oversee the implementation of the NBF; act as a clearing house for biosafety matters; and coordinate and harmonize the efforts of all concerned agencies and departments in this regard. (Draft Executive Order 2004)*

6.2.2 The Question of funding

One of the outstanding issues in the Philippines is the limited funding given for biosafety regulation. This study discovered from one member of the NCBP that the funding allocation that should have come from the National government was not met except in the early inception of the NCBP in 1990. Whilst there is a provision clearly stated in Section 5 of EO 430 that "the DOST shall allocate from its present budget such amount as may be necessary for the initial operations of the NCBP and its Secretariat... and funding requirements shall be included in the general appropriations bill submitted to the Congress," it did not materialise. The National Government was not able to provide additional budget to cope with the growing demand for the NCBP to operate effectively. The Chairman of the NCBP had to outsource funds from other means. One avenue was to tap some of the funds from the Grants in Aid (GIA) Program under the DOST. The breakdown of funds to finance the operation of the NCBP was 50% from the national government and another 50% from the GIA Program. (Panlasigue *pers. comm.*). This underpinning issue of inadequate funding was translated by others into the need for enabling mechanism for resource commitment:

> *Well, I think they (those involved in the development of the NBF) really have to put more thinking and more flesh into the enabling mechanism primarily on the resource commitment. When I say commitment it means commitment of the Departments*

[36] See Sections 4.2.1 to 4.2.5 of the Draft Executive Order (Appendix A) for a complete list of the proposed composition of the NCBP.

concerned and commitment of the National Government. I think that's where the focus should be.

The above statement implies that the problem is not the lack of funding or resources, but the allocation, commitment and prioritisation of this funding. It is surprising however, that in spite of the hype of the issue on GMO in the Philippines, the enabling resource for a biosafety regulatory regime is still at this stage scant.

6.2.3 Single Agency Regulating Biosafety

The scenario of having many different government agencies addressing the concerns over biotechnology and biosafety brought to mind the likelihood of burdensome red tape associated with it. At some stage in the development of the NBF, the need for a single window or desk in the government that will address all concerns on biotechnology and biosafety related issues was suggested and supported by several stakeholders. From the proceedings of the regional workshops obtained for this study, various structures were suggested, namely:

(1) create a single independent, higher, oversight agency or council that will oversee all biotechnology efforts from research to release stages;

(2) create a new body under the Office of the President;

(3) create a coordinating body and leave implementation to different agencies; and

(4) strengthen the NCBP by amending membership and functions, and ensuring funds for its operation (DENR-PAWB/UNEP-GEF 2003, 2004).

In the interviews conducted by the researcher, the polarity of views expressed during the regional workshops was confirmed. One government official commented that a single agency would be the ideal set-up provided that the agency can attract competent people. There are those who do not undermine the possibility of a single agency under the Office of the President.

Well I would say that would be the ideal set up provided that the agency can draw on competent people and provided that the assessment will be science-based.

That's a possibility but I think it should be under the Office of the President. I think so. Biotech is so important.

On the other hand, there are those who did not see the need for forming a separate institution outside the NCBP; they remarked that the NCBP is a functioning institution and thus it just needs to be improved and refined:

> *I think it is a good way of reviewing what we have but it should not set up as a separate system.*

> *I hope that if the biosafety framework is to be useful it should just refine and finesse the systems that are in place already, but it should not set up a separate institution or agency.*

Others were not convinced that creating a single agency would be the answer; rather forming a coordinating body is the logical approach for them:

> *I am not so sure if we need to create a single agency because the DA and DENR have the same position on this, that we don't have to create another agency but we can create a 'Coordinating Body' composed of members from the different agencies to be able to evaluate applications and see which agency should appropriately handle the applications.*

The national draft of the NBF deviated from the regional draft and proposed the creation of a National Biosafety Board or NBB whose main task is policy making. Interestingly though, in the final draft of the NBF, the NCC pushed for the strengthening of the NCBP instead of creating another layer of bureaucracy.

6.2.4 Capacity and Capability Building

The issue of capacity and capability building in biosafety especially for developing countries is considered to be one of the most urgent issues that need to be addressed (McLean *et al.* 2002, SCBD 2003). In the Philippines there appears to be a coordinated initiative for capacity building undertaken by the DA in collaboration with various institutions both international and locally; and with public and private organisations. For instance, the Biotechnology Coalition of the Philippines (BCP) with support from the United States Agency for International Development (USAID) has undertaken national capacity building activities in cooperation with the DA-Biotechnology Programme. However, it was noted by one interviewee that these capacity building efforts were limited and just starting.

The study also found that with regard to capacity and capability (in biosafety and modern biotechnology) when broke down into actual human resource, infrastructure and facility issues, more diverging views arose. One government scientist and adviser opined that the capacity for modern biotechnology and biosafety programs in the Philippines is modest compared with other countries. The scientist was basing such a claim on the reports of Halos *et al.* (2004) stating that there are about 955 experts in various fields of sciences recognised by the National Research Council (NRCP) of the Philippines and National Academy of Science and Technology (NAST). However, these pools of experts do not consist entirely of the biotechnology and biosafety spectrum; they include combined expertise in agriculture and forestry, biological sciences, chemical sciences, earth sciences, engineering fields, medical sciences, pharmaceutical sciences, and physical sciences. A former Secretary of one of the Departments of the Philippine Government argued that:

> *Notwithstanding our continuing propaganda that we have highly trained human resources, I would tell you that that is no longer true. Of the sciences, in the Philippines we are strongest in biology and biotechnology, there is no doubt about it, that is the Philippines standard; but if you compare our capacity with global standards, or even compared with our Asian neighbours such as Japan, South Korea, China, India and Singapore, we are not that strong... anyway what I am saying, when we touch on human resources is that in general we're not producing the quality of human resources we have produced before, because how can you say we are producing good human resources when our educational system is weakening. Our institutional infrastructure is also limited.*

One scientist involved in the capacity-building effort in the Philippines nonetheless, pointed out that it is not necessary to always equate biosafety capacity with molecular biology:

> *In safety assessment of course you need molecular biologists to understand a particular molecular biology event, but in doing so you also need environmental scientists - we have a lot of environmental scientists; you need food scientists – and we have a lot of food scientists too. I mean you don't need that many molecular biologists and looking at the number of applications coming in, it's not too many if you compare it with the number of applications other countries are receiving, for instance the US.*

The above statement can be construed as a short-term view of the growing biotechnology industry in the Philippines. Now that the Philippines has opened its doors to GMO propagation and importation (basically commercialisation), the Philippine officials may be underestimating the propensity of this industry to grow exponentially in the coming years.

In terms of the legal aspects, however, there is a dearth of legal expertise specifically in the field of biotechnology and biosafety. One environmental lawyer interviewed for this study reported that there are fewer than five legal experts in the field of biosafety, although there are quite a number of experts in environmental law, health and public safety, and trade law.

Experiences of the NCBP and DA-BPI showed that capacity in biosafety in the Philippines is inadequate and needs to be strengthened. The need for capacity building was stressed in the proposed NBF; it was emphasised that "to ensure the proper implementation of the NBF, the capacities of various sectors: policy makers, regulatory agencies, local government units, research community and the general public involved in performing various tasks must be strengthened (Draft Executive Order 2004)." As one member of the NCBP put it:

> *We need to have a lot of capability building the way I look at it. So as we develop more expertise in the possible benefits that can be derived, capability building also for risk assessment and risk management I think, needs to be developed.*

6.2.5 Socio-economic, Ethical and Cultural Considerations

The debate between science-based vis-à-vis socio-economic considerations in making biosafety decisions is undoubtedly a major issue in the Philippines. Accounts of the multi-stakeholder consultation process showed the opposing views of the stakeholders on the inclusion of socio-economic, ethical, and cultural considerations in biosafety decision-making. According to one participant in the process:

> *It was acceptable to some who felt that it was very important to assess the socio-economic dimensions of the technology whilst, it was unacceptable to others who felt that socio-economic, ethical, and cultural considerations have no relevance to biosafety principles.*

Indeed, there are many diverging views when it comes to the questions of science-based or socio-economic considerations in the Philippines. This study found in the report of Halos *et al.* (2004: 104) that "some scientist argued that biosafety is primarily a scientific procedure; that it specifically addresses health and environment safety, and the only objective way this can be evaluated is through a proper, science-based risk assessment and risk management process." An international scientist based in the Philippines asserted further that it would be a big mistake to consider socio-economic criteria in biosafety decision-making:

The contentious issue in the discussion of the biosafety framework is to include socio-economic criteria to allow or disallow certain products or experiments or activities to proceed. I think that's a big mistake because if it's biosafety then you work within the biosafety parameters. Whether it is economic, or whether it has to be released is another problem; but to judge it that way will complicate the whole thing because the socio-economic assessment is not that precise- there are relative scales and relative degrees of appreciation.

There are those however, who totally disagree to it being strictly science-based. One environmental scientist even put forward the idea of having a 'science-based but culture-sensitive' approach to biosafety decision making:

For me, I can subscribe to science-based but culture-sensitive. Has there ever been an absolutely pure science, I mean science tells you that we can have all the nuclear energy we want, we should have nuclear energy because it's much better according to the scientist, but the risks that measure the political acceptability of this, is not there. Now I subscribe to science-based, but I do not subscribe to limited science, as if biology and microbiology are the only sciences around...But for those microbiologists, they keep on saying and insisting that biosafety should be considered only as a scientific enterprise meaning what they are doing, within the confines of what they can understand, microbiology. Economics, ethics which they don't understand, and therefore they are not concerned with, are no longer part of science which is their science that they're talking about. To me that's an arrogant position, that I cannot also subscribe to.

For other stakeholders ethical and social considerations should be considered vital components when assessing risk and making biosafety related decisions. They were saying that biosafety could be harmful to social dynamics and social stability and therefore can cause societal harm. There are others who also believe that matters related to biosafety should be taken into the context of biodiversity of which 'bio-culture' is an extension of the latter. They emphasised that cultural minorities and their ways of life are defined by their biodiversity:

The aspect of biosafety in this country I tell you is sensitive to socio-economy and ethics. Why? Because if you look at the question of controlling the probability of harm, harm is not only physiological... a biotechnology can also be harmful to the economic system of a country and to me that's part of the regime of biosafety. It could also be harmful to social dynamics and social stability, such as why should you inject pork genes for

example into halal chicken and then sell it as halal chicken to Muslim countries. We cannot do that, that will dismantle the public approach with society. That's also a harm, to me that's also a legitimate issue on biosafety.

We should know that an extension of biodiversity in the Philippines includes bioculture - biological and the cultural because many of our cultural minorities for example, their ways of life are defined by their biodiversity.

Given the diversity of views on which path to follow, a question that can be asked is: How can one define and delineate the parameters, standards, and mechanisms for socio-economic and cultural assessments that should be followed, provided for instance that they are appropriate or acceptable? Excerpts of the NBF deliberations obtained by the researcher showed that it became clearer to most participants that socio-economic, ethical and cultural assessments are separate and distinct from risk assessment and that biosafety determination was strictly science-based. By and large, however, the use of socio-economic considerations in decision making was accepted with the proviso that there should be a careful balance in looking at the various considerations, parameters, and mechanisms for decision making. In one of the NCC meetings, it was agreed and finalised that risk assessment (or biosafety assessment as they equate it with) is strictly science-based. However, socio-economic, ethical, cultural, and other assessments in biosafety decision making should be considered prior to commercialisation, and only after biosafety assessment/determination has been made[37]. Such decision of the NCC was then reflected in Section 5.4 of the Draft EO which states:

Consistent with Article 26 of the Cartagena Protocol, concerned government departments and agencies may take into account socioeconomic considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

The NCBP shall issue guidelines relating to the conduct of social, economic, ethical, cultural and other assessments, as appropriate, particularly prior to decisions to commercialize products of modern biotechnology. These assessments shall be conducted separately from risk assessment and in a transparent, participatory and rigorous manner. (Draft Executive Order 2004)

[37] Minutes of the National Coordinating Committee meeting.

6.2.6 Transparency and Participation

McLean *et al.* (2002) highlighted that "the twin issue of public information and participation relate to the degree of transparency in a regulatory system and to the extent to which the public can provide input to the formulation either of a regulatory policy, or specific regulatory decisions." In the Philippines, observation in the field by the researcher revealed concerns over the need to further educate the people and keep the populace aware of the relevant issues, in view of the current developments in modern biotechnology. But who will take charge of educating the public and keeping the people informed? The current dilemma over deciding is which group, institution or organisation is sufficiently non-biased, and will provide balanced information to the public. One interviewee commented further that there is no mechanism that ensures the correctness, truthfulness and accuracy of the information as well as accountability. This view concurs with the report of Dayrit & Gatlabayan (2005). One top government scientist also expressed this concern and underscored the role that scientists play in communicating and explaining issues at the grassroots level:

> *I think we have to educate our people, what I'm afraid of is that when we try to move forward people will just say "We just don't want it, it's out of our culture so it's no good for us", something like that. That's what I'm afraid of. I think we really have to educate our people and see how we respect certain traditions and certain practices. Perhaps we should give a role to our scientists who can communicate, and who can bring issues down to the ground, and who can explain what the issues are.*

On the other hand, this study found that public participation occurs not just during the decision-making process for specific GMO applications but also during policy formulation. One of the members of the NCC recounted that they insisted and supported the process because they wanted to make transparency and public participation an anchor of the biosafety regime in the Philippines, which is a component of the proposed NBF:

> *Because we are a country where first of all capabilities are very low, we cannot afford to have those capabilities deposited in just one sector of society such as a government. So in that case we must make transparency and participation an anchor of our biosafety regime, and that's part of the NBF...so our NBF is anchored on our social capital and not on our technical or economic capital.*

One important inclusion in the proposed NBF is the mandate given to the National Commission on Indigenous Peoples (NCIP) to take the lead in ensuring that the rights of indigenous people and communities are recognised and protected in all biosafety decisions which affect them. In particular,

the NCIP is mandated to ensure that free and prior informed consent by indigenous peoples and communities has been given to the introduction and/or use of regulated articles within the ancestral lands and domain of indigenous peoples and communities.

Conceivably, the Philippines is taking the right steps towards engaging all sectors of the public in dealing with the sensitive issues that pertain to biosafety regulation. The next challenge will be how to implement it on the ground.

6.2.7 Access and Ownership

Another outstanding issue that was raised during the conduct of this case study was the issue of access and ownership. One environmental lawyer and a former top government official expressed the view that the real issue is not biosafety but access to and ownership of biological technologies. They were asking the question whether the Filipino people and/or the scientists themselves would be able to access the growing biotechnology; or whether the technology would remain under the control of the multi-nationals. As the environmental lawyer pointed out:

> *People are always talking about the biosafety regulation etc., they're too focused on biosafety regulations however, in the first place is there is something that we will regulate. The thing is most of the technologies on biotech are with the multi-nationals. What we are trying to say and what we want to see happening actually is that the public research institutions should acquire the capacity so that they can develop products that we need, which may not necessarily be on the priority list of the multi-nationals. So the real issue here about biotech is really access and ownership. It's not really biosafety, for us developing countries the real issue is access and ownership. Will our scientists, will our people be able to access the technology.*

A related issue that was put forward by a former top official of the government was the subversion of the economic interests of the small farmers by the multi-national seed corporations:

> *In fact in a sense the reason why people are worried about GMOs is because it is a subversion of our economic interests when the seeds of the farmers will become controlled by multi-transnational seed corporations, by a few. That's one of the reasons why it is unacceptable. They could not see it; Monsanto could not see it because American farmers can always buy the seeds. But here it's important because our farmers – looking at the future - can no longer source out genetic back-up for our agriculture from the wild assuming the worst scenario that the wild is already*

compromised; or because the growing stocks are all based on genetically modified stocks, otherwise they cannot even produce anything that can be marketed or can't compete in the market. Isn't that erosion of national security?

The displacement of farmers who rely on subsistence agriculture is another issue that was invoked by a community leader in the Philippines. The community leader emphasized that the issue is being complicated by big companies or multi-national companies buying up farmers' land which has led to displacement of many small farmers:

I think the concern is about this whole issue of big companies coming in and buying lots of lands displacing farmers, now the interesting thing with farmers is that small farmers have adopted GM technology. It's giving them an advantage in their crops, you know, they get rid of the bugs and the weevils and all sort of thinking but unfortunately I think the problem is that it becomes mixed up with this issue of big companies or multi-national companies buying up land. It actually really doesn't matter if they're buying it up for conventional agriculture or GM agriculture; it is still displacing a lot of little farmers. The issue is not too much GM; it's the issue of what to do with the farming and the poor in the Philippines, those people who rely on subsistence agriculture.

This issue of access and ownership is highly contentious. Clearly this issue merits further in-depth study and research.

6.2.8 Challenges

One of the challenges that was cited during the conduct of this study relates to putting biodiversity on top of the priority list. One official stated that the challenge is to put in place a robust biosafety regime and effective implementation of the regime for the protection of the country's biological resources:

The challenge is to make our decision makers realise that we have more to lose as far as our biodiversity is concerned because we are a priority biodiversity country; we're top mega diverse. Even if we could tap the potential of our biological resources for commercial purposes, for income generation, for scientific and research purposes we have to put in place a robust biosafety regime and effective implementation of the regime... That's the challenge. Look at other countries their biodiversity is not that high, they have less to lose, yet they are stricter in biosafety.

Another challenge according to a former Undersecretary of one of the Philippine Government Departments is for the issue of biosafety to be understood by the people so that they can have a good way of making decisions:

> *The first challenge is that people need to have an understanding of the issues so that society with its diverse interests and differences would have a good way of making a decision. It has to be understood that there are different levels of issues: the issue at the farm level, the issue at the industry level, the issue at the national level, economy level, up to global level. So it has to be understood as a multi-level, multi-sectoral bunch of issues; it's a basket of issues. If they can understand an issue the way you and I would probably understand it, then at least we have achieved something there. The other challenge would be setting up the process so that no one sector or interest group will dominate the decision; it becomes a national decision rather than an expedient decision.*

Furthermore, one social scientist put forward the challenge of implementation and the capacity to implement:

> *The next challenge and the hardest part would be the implementation and the capacity to implement. The trouble is people always criticise the regulations but they should realise that the problem as always here in the Philippines is the implementation.*

CHAPTER 7

BIOSECURITY AND BIOSAFETY ISSUES AND CONCERNS IN NEW ZEALAND

This chapter presents and discusses the crosscutting issues, concerns and challenges to biosecurity and biosafety in New Zealand. This chapter has two sections. The first focuses on the biosecurity issues and concerns and the second delves into the biosafety issues and concerns.

7.1 Biosecurity Issues and Concerns

7.1.1 Understanding the Term Biosecurity

There is no doubt that New Zealand is one of those few countries that certainly understand the whole concept of biosecurity. In the previous chapters it was shown how New Zealand's definition of biosecurity evolved from and transcended a more economic or primary production focus to a holistic focus of including human health and the environment. Based on a recent realignment of priorities, New Zealand is geared towards protecting not only its terrestrial ecosystems but likewise its marine ecosystems. In this study, New Zealand's scope of biosecurity was compared with the FAOs (2003) scope of biosecurity. Such comparison showed that New Zealand' biosecurity can be considered similar to or parallel to what the FAO encompass *i.e.* "biosecurity covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of GMOs and their products, and the introduction and management of invasive alien species and genotypes" albeit, New Zealand does not specify the other aspects that it pragmatically covers. In its definition, New Zealand did not explicitly specify the full scope of what it wants to exclude, protect and effectively manage, however, it does cover in a implicit manner a wide ranging aspect. Based on the cabinet papers, official publications, reports, biosecurity magazines, government press releases, and conference proceedings, among others that the researcher collated for the purpose of this study, it showed that the specific scope of biosecurity in New Zealand includes plant pests, animal pests, microorganisms, new organisms, GMOs, zoonotic diseases (such as BSE, SARS and Avian Influenza), plant diseases, IAS, emerging diseases such as FMD and Avian Influenza, food-borne diseases, infectious diseases and other biological threats.

Furthermore, it should be emphasized that biosecurity in New Zealand would include various measures such as: sanitary and phytosanitary measures, inspection, exclusion, incursion response, detection and surveillance, pest management (*i.e.* through national and regional pest management strategies), disease control and eradication. These measures are executed to prevent, control or eliminate those various

threats mentioned above from entering, spreading and damaging the New Zealand environment as well as its people.

The comparison between the New Zealand scope of biosecurity and that of the FAO revealed that New Zealand's scope of biosecurity, and the measures that it sets in place in managing the risks associated with it, indicate that New Zealand's biosecurity is at the forefront internationally. Interestingly, according to one senior MAF official and a leader on an international panel, the current international perception of biosecurity is quite different from the way New Zealand understands it:

> *A lot of overseas countries just don't know what biosecurity means. They ask, do you stop terrorism? They think you police, so the brand Biosecurity New Zealand which is very new does not actually work so well. The Ministry of Agriculture and Forestry is a much better brand as people know what that means. But, no, biosecurity is not well understood. Really when you're international you don't use the word biosecurity you use the word phytosanitary or sanitary, speaking about the SPS.*

A member of the Bioethics Council commented that "there is nowhere in the world that biosecurity has been taken to any depth and substance except in New Zealand and Australia." The reason for this according to another interviewee is because New Zealand benefits from its geographic isolation as an island nation and so it has managed to stay free of the significant pests and diseases that countries in continental land masses have to deal with. A MAF official opined that most New Zealanders are also becoming aware that a major biosecurity incursion like the foot-and-mouth disease has the potential to disrupt their economic, social and environmental well-being. A paper[38] prepared by the Reserve Bank and Treasury estimated that over two years, an outbreak of foot-and-mouth disease (FMD) would wipe a catastrophic $10 billion off the country's GDP and result in the loss of 20,000 jobs, whilst the economy would take years to recover. The MAF at the time of the writing of this thesis conducted "Exercise Taurus", a simulation exercise looking at field operations response and the management at the National Response Centre in the event of an FMD outbreak (Thomas 2005). Records gathered by the researcher also showed that there are, of course other high profile pests such as the painted apple moth, Asian gypsy moth, possum, pine pitch canker, southern saltmarsh mosquito, Undaria and Argentine ant among several others that are being identified as biosecurity risks and are being subsequently addressed.

[38] The Macroeconomic Impacts of a Foot-and-Mouth Disease Outbreak: an Information Paper for the Department of the Prime Minister and Cabinet, prepared by the Reserve Bank of New Zealand and The Treasury, http://www.rbnz.govt.nz/research/0130346.html

In view of the perceived biosecurity risks to New Zealand, the government has increased baseline biosecurity funding[39] by over 50% since 1999. The baseline budget for 2005 amounted to NZ $165 million (circa US $116 million) with an increase in the 2004 budget of NZ $46.5 million. This included NZ $20 million specifically for marine biosecurity capability enhancement[40]. At the time of writing, another high profile initiative was formally launched *i.e.* the plans for the creation of the National Centre of Biosecurity and Infectious Disease which is designed to provide a centralised national coordination point and enhance national capabilities and services for investigating and responding to:

(1) existing, new, and emerging animal diseases such as FMD and Avian Influenza;

(2) existing, new and emerging diseases that transfer from animals to humans (that is zoonoses) such as BSE, SARS and Avian Influenza; and

(3) other major public health concerns such as food-borne disease outbreaks[41].

One international scientist interviewed by the researcher explained that New Zealand's 100 percent screening of all passengers and crew at international airports was a procedure not present in other countries that the scientist had visited. Furthermore, biosecurity breaches at New Zealand airports, *i.e.* not declaring unwanted item(s) would incur an automatic instant fine of NZ $200[42]. This has become a point of comparison for those travelling in other countries; they concede that New Zealand takes biosecurity more seriously than other countries even in the US and Europe:

> *I haven't encountered biosecurity of any substance anywhere except in New Zealand and Australia and the Pacific. Even America doesn't care, you can go in and out of America and they don't inspect you; they want to knock you back if you're a terrorist but they're not that worried if you bring something that will kill off their crop. In the European Union it's the same thing, I have never ever been inspected, even my luggage, between countries. Even when I entered the EU which I normally do through Rome they have never checked me. So you know New Zealand and our part of the Pacific countries, Papua New Guinea, Tonga, places like that, all have biosecurity.*

[39] Baseline funding is the funding given yearly but does not include funding for one-off incursions.
[40] Press Release by Hon. Jim Sutton. International marine bioinvasions conference, Wellington. www.beehive.govt.nz/ViewDocument.aspx?DocumentID=24049. Date retrieved: 14 September 2005.
[41] Press Release by Hon. Jim Sutton. Launch of plans for new Wallaceville centre. www.beehive.govt.nz/ViewDocument.aspx?DocumentID=24050. Date retrieved: 14 September 2005.
[42] Press Release by Hon. Jim Sutton. Government boost biosecurity again. www.beehive.govt.nz/ViewDocument.aspx?DocumentID=23121. Date retrieved: 14 September 2005.

The above simply indicated the level of seriousness that New Zealand places on protecting the country from biosecurity threats. The level of funding that the New Zealand government has poured into biosecurity activities reflects the level of commitment that the country has to biosecurity.

7.1.2 Biosecurity System

The archives collated by the researcher showed that New Zealand's biosecurity system evolved from a sectoral approach (*i.e.* animals, forest, plants, policy and international) to a whole-of-system (*i.e.* across sectors and agencies), and point of intervention approach (*i.e.* the pre-clearance and post-clearance). Such focus has shifted in view of the Biosecurity Strategy's overall expectation that "the biosecurity system should be fully integrated, and operating efficiently and transparently in an environment of continuous improvement." As a result, MAF held the overall responsibility for biosecurity; in part the underlying reason was to reconcile the issue of prioritisation[38].

This case study embarked on learning the perceptions of some key people on what they thought of the whole-of-system approach vis-à-vis the sectoral approach after an almost a year of implementation of the new biosecurity system. Most of the officials interviewed agreed that the new system is the best way forward. They argued that in the whole-of-system approach there are better synergies and better efficiencies across sectors. They also felt that looking at points of intervention is better because it gives everyone the opportunity to look across the system and make better and calculated decisions about where priorities sit in terms of both excluding pests in the country in the pre-clearance criteria; and deciding how to manage those pests that have got through the border security. One MAF senior official emphasized that it gives them the opportunity to review the systems in place, begin improvements in some areas, fill gaps and ensure that a full range of values is taken into account:

> *It is obviously the best way to go and we should have always been doing it, coordinating between sectors. There's no argument that you could have just coordinated sectors better, but in reality it's better, you get better synergies you get better efficiencies if you coordinate across and side-to-side. But it has also given us a good opportunity to review our systems, where to begin improvements in some areas, fill gaps to make sure there are no holes in the system so it is much better the way we are now, the way we're growing now.*

In terms of operational level, one senior policy analyst pointed out that it is better to make informed decisions when people from the plants group understand the issues the animal group has and vice versa, hence, better decisions and prioritisation can be made.

When the government adopted the Strategy last year, the first things that resulted from it were the structural changes and some shifts in accountability. The accountability is now being left with MAF for the biosecurity system as a whole which means it is not just the central government, but includes regional government and industry as well. MAF now has to look at the overall coordination and consistency across the system and deliver a range of outcomes which include the economy, trade, environment, health, cultural and Māori objectives. In view of what MAF and other agencies have accomplished so far, in line with their new role, one official remarked:

> *I think that the department and agencies have actually made a lot of progress in the course of less than a year of trying to take that view. We got secondments from the Department of Conservation and Ministry of Health in the Biosecurity Strategy Unit; there are secondments from the Department of Conservation in Biosecurity New Zealand; and that is one way of getting this thing integrated. I think that, yeah, there has been really quite a lot of progress in the short time.*

On the other hand, there were officials who commented that they have not seen any evidence yet in terms of new focus on pest management. In the new system, MAF is supposed to provide the over-all leadership in pest management; nonetheless, they admitted that it is certainly just in its early stage on that front. Obviously, in terms of how successful the new system will be, time will certainly tell. On the other hand, one former official commented that whilst New Zealand has moved to the points of intervention approach, other countries and equivalent organisations are still structured on a sectoral basis with the distinction between plants, animals and forestry. The official is concerned about how New Zealand would relate to its equivalent organisations in other countries who themselves might be confused with the new arrangements:

> *When I see equivalent organisations in other countries all still structured on a sectoral basis, in particular with the distinction between animals and plants and forestry; and likewise I also see the international standard setting bodies essentially running on a sectoral basis – you have OIE for animal health, animal disease standard setting role and advisory role; you similarly have the Interim Commission for Phytosanitary Measures (ICPM) which is the equivalent one on the plants and forestry side; and so I have concerns based on the international theme and how well New Zealand can therefore relate to its equivalent in other countries...everything is still simply based on sectors and as such I'm not yet convinced that MAF will be somewhat apt-think with other operation.*

It would be considerably interesting to follow through the development in the whole-of-system approach that New Zealand has recently adopted. The merits and demerits of such a system will certainly be unfolding in the coming years.

7.1.3 Risk Analysis and Integrated Risk Management Framework

Based on the recent Memorandum of Understanding (2005) on biosecurity activities between MAF, DOC, MFish and MOH, it was emphasized that biosecurity decisions will be informed by science, evidence and best knowledge available, using appropriate precautions. It stated further that the biosecurity system should be based on assessing, prioritising and managing risks. This implies a science-based risk assessment. But this study learnt from one former official of MAF that risk assessment (the way MAF employs it), should be viewed into its completeness which is the risk analysis. Furthermore, risk analysis would then serve as one of the bases for risk management. According to a senior adviser from MAF, if when they carry out risk analysis they follow a science-based process that will take into account all potential impacts, even social impacts but from a scientific viewpoint; then risk management will follow. The official referred to risk management as the decision making process that takes into consideration the product of risk analysis and weighs it together with other values such social, political and the range of values important to New Zealand. As the senior adviser explained:

> *So what we are trying to do here is separate very carefully, separate risk analysis-science from politics because if politics contaminate the risk analysis-science process then you'll start getting the wrong answers. Now with risk analysis you can get an answer and then politics make different decisions but at least you know your trails, you know where you've sacrificed, you find default for political answer. If politics affect risk analysis you contaminate the decision, the answers if you like, you can contaminate the outcome of risk analysis – you don't know what you don't know, you don't know what you're not doing properly and that's quite risky. So it's better to have risk analysis-science to avoid political interference which is the way biosecurity has been written basically, then have you risk management political decision making process separate.*

Most of the recommendations in the Biosecurity Strategy aim to create a single, holistic and integrated biosecurity system which is where the new concept of Integrated Risk Management Framework IRMF) is anchored. This study found that biosecurity IRMF will be used to guide decision-making for all activities where MAF is accountable for service delivery. In addition, the Chief Executive Forum has noted its intention to use the IRMF to inform decision-making on resource allocation in managing

biosecurity risks across the biosecurity system, and to support the system's oversight role (MOU 2005). One official of MAF provided an elaboration of this relatively new concept:

> *The Integrated Risk Management Framework (IRMF) is basically a decision making tool. Integrated risk management framework is about decision making so if you like, you deal with your risk analysis when you have a whole set of potential options for decision making; how you make that decision you apply the IRMF around that decision, so you'd say which option is the best option which is the most cost effective, which encompasses New Zealand's values, that's your IRMF about decision making. so the feed-in to the IRMF the risk management framework you have to have information, you have to have good information and risk analysis is one area that generates that good information, you have to have the resource of other information, other values cost benefit, all sorts of stuff have to be generated as well (for informed decision making) for informed decisions, exactly.*

The way New Zealand manages risks will be vital in terms of delivering the outcomes it sets out to achieve. Employing the principle of comprehensive risk management and the adoption of the IRMF are considered vital in meeting those outcomes. The researcher did not investigate further the way IRMF is being used by other agencies and sectors involved in biosecurity in New Zealand, but it would be worthwhile to look closely at its mechanisms and how this framework impacts on the decision-making process for biosecurity matters in New Zealand.

7.1.4 Pest Management

The issue of pest management in New Zealand is one of the issues that surfaced during the conduct of this case study. The issue of rationalisation of Regional Pest Management Strategies (RPMS) was put forward by one environmental scientist and a senior lecturer. They proposed that there should be a set of recommended best practice protocols in pest management that can be used in controlling pests by the different regional councils. They stressed that rather than re-inventing the wheel, these sets of best practice protocol can be followed and adopted in particular regions. Such an idea can be best understood in the example provided by the environmental scientist below:

> *Whilst I think the regional pest management strategies are a strength in the different regions considering priorities, what I think needs to be set in place is: if Northland is going to have "cordoned areas" in one of the pampass grasses – the plant they want to control, and so is Waikato, that you don't see two completely different sets of approach.*

Another issue that this study gathered was the issue of "super regional approach" that was put forward in view of pest management. Such an approach was proposed by a biosecurity specialist and described as a North Island and South Island pest management strategy that strategically controls a particular pest[43] which could be a problem either in the North Island or in the South Island.

7.1.5 Amending the Biosecurity Act

In view of implementing fully the new biosecurity system, the issue of potentially amending the Biosecurity Act was raised. One senior MAF policy adviser interviewed for this research pointed out that the Biosecurity Act is quite a well designed piece of legislation and that it does not require amendment at this stage. Other officials interviewed agreed that the Biosecurity Act is a stable and empowering piece of legislation and that no rework is needed. They added that the Biosecurity Act actually does not specifically mandate what to do but rather provides the framework and powers to do what needs to be done. One official further stressed that it is possible to change the whole system and the Biosecurity Act would still be relevant; and stated categorically that was what happened in view of the new biosecurity system in New Zealand. A former MAF top official and a senior policy adviser to MAF supported this view and expounded their insights below:

> *I think in domain the essentials of being able to operate the biosecurity system have been established in the Act and the necessary powers are there.*

> *It (the Biosecurity Act) actually establishes some processes for considering the set-up and processes; for how you would consider the importing of products and managing the risk of importing products into the country. It sets-up some systems and provides some powers so that we can respond to the new pests that arrive into the country; it also establishes some systems for deciding how to manage pests, those ones that are in the country, whether it should be done regionally or nationally, or by individual land owners... it's a process – based system; it's got the ability to recover cost and to set up funding arrangements... So I don't think it will need a major rework, it might just need some slight refocusing of the legislation.*

On the contrary, one government strategist opined that the Biosecurity Act needs changes or amendments (if the government is willing) in view of the biosecurity restructuring, the Biosecurity Strategy and the interface between the Biosecurity Act and the HNSO Act. It was stressed by the

[43] One example that was cited was the case of the Varroa Bee Mite.

official that what the Biosecurity Act does is to provide a range of tools, but does not actually say who should be using those tools and for what purposes.

7.1.6 Biosecurity as Strategically Important as National Security

The Parliamentary Commissioner for the Environment in its review of the biosecurity system reported that "biosecurity is not recognised as being as strategically important to New Zealand as national security" (PCE 2000: 9). In this case study, it was attempted to bring back the issue and some people were asked their views on and insights into this particular concern. One official commented that people just need to look at the recent experience with Operation Waiheke[44] to see how important biosecurity is in New Zealand. Another official did not give a direct answer but commented that biosecurity has obviously gained prominence in New Zealand and that its prominence is significantly increasing. One senior advisor to the government further emphasized that biosecurity has become a bigger issue in New Zealand and has become a bigger word, so to speak:

> *What's becoming more understood now is that biosecurity impacts on many, many more things than was originally envisaged; originally it's basically a productive sector issue, now it's being recognised as environmental, social, health, across the spectrum with impacts on lots and lots of things... so it's recognised as being something that impacts right through New Zealand and that reflects the broader mandate of Biosecurity New Zealand. We're here to protect not just parts of New Zealand but the whole thing. So I guess what's been changing is that biosecurity really is now considered to be the whole biosecurity if you like; the whole thing is now being envisaged, rather than in the past it's smaller biosecurity, it becomes a much bigger word now.*

7.1.7 Biosecurity Encompassing Biosafety

The idea of biosecurity encompassing biosafety[45] is being promoted in a recent FAO Committee on Agriculture (COAG) meeting (FAO 2003a). In terms of the international scene, one government scientist who also represents New Zealand in international panels in agriculture commented that biosecurity and biosafety overlap to some degree. The scientist emphasized that there is a need for some form of international coordination on that front. However, the scientist stressed that it should not create duplication and another level of bureaucracy:

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[44] Operation Waiheke was the action taken by the government led by MAF Biosecurity New Zealand in coordination with the Police and New Zealand Food Safety Authority, related to the claimed deliberate release of FMD virus on Waiheke Island sometime in May 2005; it turned out to be a hoax.

[45] Biosafety is referred in this case study as the regulation of the introduction and release of GMOs into the environment; or as SCBD (2000) defines it as the need to protect human health, and the environment from the possible adverse effects of the products of modern biotechnology.

But what you don't want is duplication, you don't want a whole separate set of bodies; it becomes like bureaucracies at the FAO level. So you really want it to be limited, try to look under one or two frameworks rather than numerous frameworks.

In New Zealand, a senior official of MAF noted that the encompassing nature of biosecurity over biosafety is happening to some degree, in view of the current biosecurity system in place. The official stressed that MAF and ERMA may have different foci in dealing with new organisms but they all fall within the broader biosecurity context:

Well in New Zealand it does. From New Zealand's perspective – Biosecurity New Zealand which now looks after the whole-of-system biosecurity also does a lot of biosafety stuff in coordination with ERMA of course. MAF and ERMA have different foci in dealing with new organisms but it is all biosecurity; it's all part of the same game.

Moreover, according to a senior policy analyst and a MAF official there is a need to differentiate between the policy and risk assessments and the tools for delivering biosecurity and biosafety. For them the tools delivering biosecurity and biosafety are basically the same, *i.e.* the border control, the inspection, the audit, among others; hence in that sense there is some form of encompassing mechanism for biosecurity over biosafety.

7.1.8 Challenges

One of the challenges that was raised during the conduct of this case study in view of biosecurity was on addressing the continuing incremental loss of biodiversity. One senior lecturer of one of New Zealand's top university institutions commented that New Zealand is still facing a major problem in the conservation of its flora and fauna. According to the lecturer, whilst the biosecurity focus has shifted from a more production oriented one to consideration of biodiversity values, still there are losses on a daily basis of New Zealand's valued species. There were comments that support this concern. One interviewee commented that people do not perceive it as a multi-billion dollar industry and it does not have quite the same amount of focus yet compared to the economic values. They believed that the single largest problem still lies in the conservation state. Another related problem that was put forward was the possum problem and its role in spreading Bovine Tb. However, related to possum control, one of the challenges identified was the international perception of how New Zealand controls it; the use of

1080 as poison to control possum for instance has been the subject of debate[46]. In relation to the possum control problem, one environmental scientist further opined:

> *It's not only a biosecurity threat per se, but it is a threat to our economy, our national security if you like, and to broader environmental security.*

Another challenge that was brought up was the increasing urbanisation and the changing immigration pattern in New Zealand. One people's organisation representative commented that the immigration pattern from Asia, the Pacific and even from Europe is an emerging concern since most of the people that come from these countries do not understand the level of biosecurity that New Zealand has. As the representative put it:

> *I think part of the question is around the change in the immigration patterns to New Zealand and I think the immigration patterns now from Asia and from the Pacific and even from Europe where they don't have anywhere near the strong biosecurity regulations that we have, they simply don't understand. They're coming from cultures that don't understand this level of biosecurity at the border, and so as a result you get people bringing all sort of things in their bags, in their belongings you know; and we do our best to catch them but the fact that we've had a number of unwanted things brought into New Zealand is probably evidence that it's going to be something like we'll be running constantly to a standstill in terms of keeping up with it.*

The above challenge linked up with another challenge that was identified by a former MAF official:

> *I think the biggest challenges may well relate to effective communication and engaging the relevant sectors.*

7.2 Biosafety Issues and Concerns

7.2.1 Biosafety Systems In-place

This study found that prior to 1996, there was no law in New Zealand specifically dealing with GMOs and its potential release to the environment. There was confusion too on whether microorganisms were covered under any legislation (Moeed *pers. comm.*). There was legislation in place but it did not have coverage for assessing environmental effects. Archived records revealed that in 1998, the Minister for

[46] ERMA reported in its Statement of Intent 2004/05 that hazardous substance decision-making in 2005 will be dominated by the anticipated application for the reassessment of the vertebrate poison 1080.

the Environment had set up a body called the Interim Assessment Group (IAG), which reviewed proposals to field test or release GMOs. However, the IAG had no statutory basis. Its review was mandatory for government-funded research and voluntary for privately-funded research (Pollak 2003).

This study also noted that in view of the current biosafety system and the recent amendments made to the HNSO Act, many believe that the system is working well primarily in terms of regulating GMOs. The case-by-case regulating mechanism that was set in place is a welcome mechanism for some people. One government official remarked:

> *We have quite a good regulatory system for genetic modification. The Environmental Risk Management Authority (ERMA) is good. The legislation actually sets in place a body that regulates or controls on a case by case basis as do ERMA and Assisted Reproduction Legislation, and the reason for that is simply that you can't actually legislate from much of this technology in detail because you have no idea how it will actually develop, and changing legislation takes a long time whereas changing regulations or changing how a regulatory body acts is much quicker, so that's been the response: to develop sort of a legislation that sets the body in place to do it rather than trying to legislate in detail.*

Furthermore, this study found that the improvement to the way the biosafety system operates in New Zealand was influenced by the current changes in the legislation. The amended legislation (HNSO Amendment Act 2003) gave effect to the findings of the Royal Commission on Genetic Modification and enabled ERMA to strengthen its decision-making framework for GMOs; streamlined the approval process for low-risk GMO laboratory work; established a Maori Advisory Group under the Authority of ERMA; and improved the enforcement[47] mechanisms for new organisms.

7.2.2 Socio-economic, Ethical and Cultural Considerations

Science-based versus socio-economic, ethical and cultural considerations in risk assessment and biosafety decision-making has been a contentious issue even in New Zealand. Economic, cultural and ethical considerations which are part of the definition[48] of environment in the HNSO Act mean "that the variety of environmental effects ERMA must consider is large, going well beyond the range of physical and natural phenomena that science is prepared to measure and predict" (Pollak 2003: 52). According to one ERMA official, the HNSO Act is a very comprehensive legislation so that, given its broad definition of the environment, everything must be evidence-based and the words "in my opinion"

[47] This was also an offshoot of MAF and ERMAs response to the recommendations of the McGregor Report.
[48] The complete definition is given in detail in the succeeding section on transparency and public participation.

and "I think" are not acceptable. But how do you put or integrate socio-economic, cultural, and ethical considerations into making a decision to accept or deny the introduction and release into the environment of a new organism, for instance? The official from ERMA provided a mechanism that they employ in the Agency which is more on balancing the risk against the potential benefit:

> *It is very broad what we have to do on our risk assessment and it's all based on evidence but the evidence might be in my 'iwi' this particular organism is 'taonga' so it's special. Ah, if you are going to do something that could harm my 'taonga' that has a cultural impact on me as a Maori and we have to take that evidence and look at it alongside everything else and put it into the risk assessment. And at the end of a process what the Authority has to do is weigh up the benefits of the use of the new organism vs. the risk. So the cultural risk affecting the 'taonga' has to be weighed up against the potential benefits and it could be that the 'iwi' is being adversely affected so one community is adversely affected, the research community might be positively... so we need some balancing and the way we're trying to manage that is by using control or conditions to mitigate any of the adverse effects. So we manage the adverse effects to bring them down to what we call a negligible level.*

Whilst ERMA employs evidence-based decision, this study also learnt of another term. A senior lecturer put forward the idea of making a value-based decision. It was emphasized by the lecturer that it should be multiple value systems running parallel and the decision must be based across a whole range of values:

> *I would like to see both or multiple values systems running parallel. So what I'm saying is that science can inform us only, science isn't necessarily making a value-based decision. So the science provides us with answers to questions about how big a problem is it going to be, what types of impacts are they going to be, where is this pest likely to establish, what is it, what is its biology, what is its life cycle, science provides us with answers on what sort of toxin or what sort of control approach could we take here. Science does not answer the question of should we control, which ultimately comes back to a value-based decision, will it be cost-benefit economic type decision, or will it be a cultural decision, a value-based; society sees it as a whole set of priorities so we should control it. Well I mean science can help inform good management it should not be science driving the decision in the first place because a decision is a value-based decision and that's going to be across a whole range of values: it's going to be economic values, it's going to be social values, and science helps answer whether it's technically feasible.*

Similarly, one former MAF official supported that idea:

> *I believe that the approach to risk assessment would in its completeness – risk analysis, has to be supported by science but inevitably the values that a country puts on particular aspects will differ and so sort of socio-cultural matters have to be taken into consideration...so inevitably there are going to be those judgments that are based on the values and cultural basis of the country and I think there needs to be a risk analysis framework that takes that into account.*

Nevertheless, the question of how to incorporate social, economic, and cultural values into a risk assessment, or in biosafety decision making considering such inherently intangible values, was a persistent. A top government official and a member of the Bioethics Council provided two separate answers that arguably offer some form of mechanism to going over these intricate issues. The former made mention of ERMA's proposed framework[49] for cultural, ethical and spiritual issues whilst the latter talked about how the Bioethics Council is addressing the issue:

> *Actually and basically safety issues for both people and the environment can be decided by scientific risk assessment; but cultural, ethical and spiritual issues are not able to be set into that type of framework which is why ERMA has now developed a particular framework for them. You can't, if you push the cultural, ethical, and spiritual issues into the risk framework you really distort them, like for instance, how much of the risk is it to your spiritual nature, this kind of thing you know. I think it's quite interesting to see that ERMA after about ten years of operation and initially beginning its life as purely a science and risk assessment organisation has now moved to a point where it feels it needs a framework to deal with these issues.*

> *I guess our framework is our method, that our terms of reference from the government require us to engage with the public on these issues and find out how New Zealanders feel about it; also, to get New Zealanders to talk to one another about it. So not just to tell us what they think but to talk to one another about it, so therefore we have these dialogue events. Our methodology is really about getting people to talk together, people from different viewpoints to talk together about the issues and then we analyse what we hear and then we think about it and reflect on it ourselves and come up with recommendations or advice to the government.*

[49] At the time of writing this thesis, ERMA has set a draft framework for dealing with ethical, cultural and spiritual issues and they have put it out for consultations. It was posted on their website: www.erma.govt.nz.

7.2.3 Transparency and Public Participation

Transparency and public participation (as this study gathered) particularly in the field of biosafety and genetic modification have been major issues in New Zealand over the years. Chapter 5 of this study showed that New Zealand is one of those countries that incorporated the broader objectives and consideration of social, economic, and cultural factors in the law – *i.e.* the HSNO Act. Under the Act, "environment" is defined to include:

> "(a) ecosystems and their constituent parts, including people and communities; and
>
> (b) all natural and physical resources; and
>
> (c) amenity values; and
>
> (d) the social, economic, aesthetic, and cultural conditions."

The Act also requires that all decisions take into account, among other things, the sustainability of flora and fauna, the intrinsic value of ecosystems, public health, and economic and related costs and benefits from the use of new organisms. Furthermore, decisions must take into account the relationship of Māori people and their culture and traditions with respect to their ancestral lands, sacred places ("waahi tapu"), valued flora and fauna, and other "taonga" (which translates roughly as "treasures"). Decisions must also take into account the principles of the Treaty of Waitangi. In addition, all persons exercising powers and duties under the HSNO Act must "recognise and provide for" "the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations." Whilst the philosophy of the HNSO Act covers the public process, one top official of ERMA clarified that they do not include public consultation in every application. The official also clarified that whilst the HNSO Act requires public notification for all field tests of new organisms, it is at the Authority's discretion to notify the public on containment applications:

> *The philosophy of the HSNO Act is that it includes the public process, now we don't include public consultation in every application that we have. So for example the containment application, especially the low-risk containment application, there's no public consultation; however, there is a Maori member and a lay member of the community who sits on the Institutional Biological Safety Committee and they are representing the views of their community. Now, the HSNO Act requires that all new*

organism releases are publicly notified and also all field tests, and the Authority has the discretion to publicly notify containment applications. And so we have some test that we apply to that discretion around the public interest, how strong would be the public interest in that particular type of application.

One member of the Bioethics Council commented that for New Zealand transparency and public participation are really important, but pointed out the problem of limited transparency. The official stressed that what the public expects is to have a voice in shaping the way the technology develops:

I think for New Zealand they are really important. With regard to transparency, transparency always has issues around it, something to do with commercial sensitivity; that's often a problem in relation to transparency 'cause you won't get information about forms of technology because they are commercially sensitive, you know somebody is going to undercut the price of something or find out their method or whatever if they are made public. So that's always quite a big issue in terms of transparency but I think it's what the New Zealand public expect and they also expect to have a voice in shaping how that technology develops.

7.2.4 Māori Issues

This study found that Māori issues are significant issues in New Zealand. The Royal Commission's Report (2001) confirmed that many Māori felt their opinions were not taken seriously enough or considered early enough in the decision-making process on new organisms. The New Zealand government carried out consultation with Māori in view of the Royal Commission's recommendations and those recommendations were seriously taken into consideration and formed part of the recent amendment of the legislation (HNSO Amendment Act 2003). The researcher gathered and collated several proofs of how the issue of Māori has been taken account.

The 2003 amendment of HSNO established the Ngä Kaihautü Tikanga Taiao or the Authority's Māori Advisory Committee. Ngä Kaihautü (the members of the Advisory Committee) provides advice and assistance to the Authority on matters relating to policy, process, and applications. Furthermore, the amended Act explicitly allows knowledge and experience of the Treaty and Tikanga Māori (Māori beliefs) to be considered as qualifications for appointment to the decision-making body of ERMA - the Authority. The law requires that the Authority contain a balanced mix of knowledge and experience in matters likely to come before it. The Toi Te Taiao or the Bioethics Council, which was formed two years ago as a ministerial advisory committee that provides independent advice to the government on biotechnology issues involving significant cultural, ethical and spiritual dimensions, also considers

Māori concerns. One of theirs tasks is to demonstrate their commitment to the Treaty of Waitangi including its responsibility to consult and engage with Māori in a manner that specifically provides for their needs[50]. A committee member of the Bioethics council substantiated this aspect:

> *We have some issues around Maori and biotechnology to deal with because there are lots of questions for Maori around whether their "Tikanga" which is their sort of framework for understanding the world, whether that can be expanded, whether it can develop to encompass new developments in biotechnology or whether in fact this is kind of a set group of principles that can change and would possibly lead them to oppose various forms. So is their body of lot knowledge - their Tikanga, is that able to grow and expand with biotechnology, or is it immutable, unchangeable. So that's something the council has to work through, because every biotechnology issue we come up against, this issue with Maori themselves haven't yet work-out, throughout. So hopefully one of the things we will be able to do is to help them facilitate doing that in some way, so that's one issue. We are also dealing with a Treaty relationship within a country between the indigenous people and the Crown, and where there's constant friction between Maori and the scientific establishment over how biotechnology should develop, so some of those issues need to be worked out.*

7.2.5 Challenges

One of the challenges that was identified in this study in view of regulating new organisms (which include GMO), was on knowing what is actually present in New Zealand. It circles on the question of the presence of organisms in New Zealand and thus their coverage or not, by the HSNO Act. According to an ERMA official, there has been no full cataloguing yet of every organism that is present in New Zealand. The official further opined that what is lacking is the sort of baseline information for organisms present in the country before 1998:

> *Baseline information, yeah it's a big challenge for us, especially if things get smaller and smaller.*

In addition, another challenge that was put forward was the difficulty of having sufficient or adequate information on the organism's biology and characteristics to be able to make judgment in terms of whether and how it would be established in New Zealand (Moeed *pers. comm.*).

[50] http://bioethics.org.nz/about-us/terms-of-ref-english.html

Another important challenge for ERMA is monitoring and coordinating compliance (Pollak 2003). Based on the recent independent review of ERMA, "monitoring and co-ordinating compliance with the Act and Authority decisions has been patchy... The emphasis of Agency effort in new organism work is so strongly oriented to processing applications that the recurrence of monitoring mishaps cannot be ruled out" (Nakhies *et al.* 2003: 50). This view was supported by an official interviewed for this study suggesting that monitoring and compliance are two areas where ERMA needs to advance and gain more strength and experience.

CHAPTER 8

CROSS-CASE ANALYSIS OF BIOSECURITY AND BIOSAFETY SYSTEMS AND ISSUES IN THE PHILIPPINES AND NEW ZEALAND

This Chapter presents a cross-case analysis of the biosecurity and biosafety systems and issues in the Philippines. The issues and concerns covered in this analysis are only those main issues where substantial comparing and contrasting can be made. The other issues not covered in this cross-case analysis are included in the last Chapter – Chapter 9 where synthesized concepts and lessons from the field are outlined.

8.1 Biosecurity System

8.1.1 Understanding the Term Biosecurity

Evidence from the field revealed that there are distinct differences in terms of the way the Philippines understand biosecurity compared with New Zealand. In the Philippines, it is still unfamiliar terminology and is sometimes confused and used interchangeably with the term biosafety. There is no direct definition of the term biosecurity in the Philippines, though some people associate it with preserving biodiversity, or under the term environmental security. Biosecurity as a matter of terminology may be relatively unfamiliar to the country but when broken into its associated risks, a better understanding of it emerges. There is a growing awareness of and concern about the current threats brought by high profile cases of SARS, Avian Influenza, BSE and FMD. This level of understanding of the term biosecurity in the Philippines connects with the claim made by FAO (2004) that biosecurity issues remain inadequately understood or addressed in Asia.

In New Zealand on the other hand, the term biosecurity is understood to mean exclusion, eradication, and management of risks associated with pests and diseases. It is also understood in terms of activities associated with it such as inspection detection and interception at the border; surveillance and incursion responses; and national and regional pest management. The scope of biosecurity in New Zealand and the range of values it wants to protect are parallel to the FAOs (2003) coverage of biosecurity.

8.1.2 Enabling Policies and Legislation

In terms of policy, there is a big difference between the two countries. In the Philippines, there is no biosecurity in place but technically it could be anchored loosely to the general policy provided under the Philippine Agenda 21. The problem however, is that the Philippine Agenda 21 in itself remains

under fire because it has fallen short of the great expectations of the Filipino people (PCSD 2004). The review and assessment conducted by PCSD revealed the limited scope of the Philippine Agenda 21 and its generally perceived low impact. New Zealand on the other hand, used the Biosecurity Strategy as a comprehensive mechanism and platform to direct policy direction across the biosecurity system. It sets the policy in terms of recommended steps and medium to long term expectations. The policy for biosecurity in New Zealand is straightforward and has a whole-of-system focus.

Both the Philippines and New Zealand have primary legislation in place when it comes to addressing biosecurity concerns. The difference however, is the directness of the legislation in terms of addressing biosecurity concerns in each country. The Philippines has a fairly elaborate legislation (mainly primary legislation) that contains specific provisions of relevance to biosecurity regulation. The issues encompassed in biosecurity are traditionally and separately dealt with in the Philippines in terms of food safety law, plant and animal quarantine law, wildlife law, fisheries codes and pesticides regulations among others; and are administered and implemented in two major government departments – the DA and DENR, and their respective attached agencies and bureaus. These laws to some extent provide mechanisms to regulate pests and diseases from entering or spreading into the country. However, whilst these laws address the problem of pests and diseases there are questions in terms of implementation and enforcement mechanism of the laws. In a sense, the legislation in place is a minimum requirement for trading countries like the Philippines. The degree of its implementation and enforcement are arguably in question.

In New Zealand, the Biosecurity Act is a stable and empowering piece of legislation. The legislation itself sets the framework, systems and processes and provides a process-based system that has the ability to recover cost and set up necessary funding arrangements. The New Zealand biosecurity law provides for comprehensive management of pests and eradication of pests which are significantly lacking in the Philippines legislation. The enabling provision for enforcement and liability and redress are also the strength of the New Zealand law on biosecurity. The interface of the Biosecurity Act with the HNSO Act however, as found in this study, needs resolution on particular arrangements concerning unintentional introduction of new organisms. This supports the comments made by Walker (2005).

8.1.3 Governance and Regulatory Frameworks

The biosecurity governance and regulatory framework in the Philippines and New Zealand are two interesting cases. In the Philippines, the biosecurity governance and regulatory frameworks are scattered among different sectors involving agriculture, forestry, fisheries, health, and trade and industry. They are also generally limited to food safety, and plant and animal quarantine regulations and activities. Interestingly though, New Zealand for many years followed a sectoral approach to

biosecurity *i.e.* plants, forestry, animals, policy and international, which, although not exactly the same system, is the present position of the Philippines. The level of coordination, prioritising and the strategic and operational focuses were considerably different when New Zealand was still applying the sectoral approach. There is a clear indication that the Philippines needs a coordinated national framework to regulate and manage biosecurity matters.

In the case of New Zealand, since the biosecurity system recently evolved from a sectoral approach to a whole-of-system approach to biosecurity, it will be interesting to see how the new system will deliver in the future. Certainly, MAF will be the focus of the way an integrated, across-system and side-to-side approach to biosecurity develops and responds. This current biosecurity governance and regulatory framework in New Zealand is an ideal situation; however, biosecurity decisions made by one Agency may have implications for other agencies accountabilities and operations. The notions that the whole-of-system approach will provide better synergies and better efficiencies across sectors are yet to be proven in the not so distant future.

8.1.4 Issues in Pest Management

There is a significant contrast in the way pest management is being handled in the Philippines and New Zealand. Pest management in the Philippines is predominantly farmer-led pest management through Farmer Field School. The country does not have a national or regional pest management strategy; instead what it employs is the creation of *ad hoc* committees or task forces to address the problem with a particular pest. There is an absence of authentic experience or programs to eradicate pests in the country. Furthermore, the focus of pest management in the Philippines is more on agricultural crops and reducing the use of pesticides. The current dilemma is how to address other pests such as animal pests, forest pests and invasive pests (which could be plants, insects, fish or other organisms).

In New Zealand, managing pests is quite different. There are national and regional pest management strategies in place guided by primary legislation. There are multiple actors or stakeholders involved in implementing the pest management strategies and activities in New Zealand which include the national government, regional councils, the Animal Health Board, farmers, industry sectors and Crown institutions. Whilst the Philippines has no authentic eradication measures in place, New Zealand on the other hand, has numerous pest eradication initiatives and activities. Notably, New Zealand was successful in terms of totally eradicating high profile pests in a particular locality or in its wider environment. The current issue on pest management in the country however, is the need to rationalise its national and regional strategies and activities.

8.2 Biosafety System

8.2.1 Enabling Policy and Legislation

The foundation of any biosafety regulatory system is the enabling legislation (acts, laws, decrees, and government orders) governing biosafety (Mc Lean et al 2002). Both the Philippines and New Zealand have policies, legal instruments, and regulations in place to regulate biosafety matters primarily GMOs. In the Philippines, the legislation in place is secondary legislation in the form of Presidential Executive Order (EO 430) and a Department Administrative Order (DA AO 8). This approach to legislation has been adopted on account of the novelty of and rapid developments in modern biotechnology and the need for a quick and flexible response at the time. Legislation in the form of EO and AO is easier to approve and amend than laws. New Zealand on the other hand, has primary biosafety legislation in the form of a statutory law – the HSNO Act; but also has a stringent regulation in place administered by ERMA.

There is congruence in the way the scope of biosafety legislation for both countries developed over time; the underlying focuses however, are slightly different. The scope of the Philippines biosafety regulation has developed over time in a phased manner; it started from laboratories and contained experiments, then extended to covering field trials; then more recently covered release into the environment for propagation and commercialisation. When EO 430 was issued it was aimed at creating a body and a national policy on biosafety that would regulate all biological activities that may be potentially hazardous to plants, animals and humans, however the underlying focus then was towards regulating importation, transfer and use of GMOs and PHES. On the other hand, the HSNO Act was created in view of the need for a criteria-based legislation that would apply to all new organisms that are coming into the country, whether they are microorganisms, plants, animals or GMOs.

8.2.2 Governance and Regulatory Frameworks

Both the EO 430 of the Philippines and the HSNO Act of New Zealand created an Agency or a body to implement the legislation and regulations that were set in place. The Executive Order 430 created the NBCP whilst the HNSO Act established ERMA; there are differences though on how the two institutions are empowered, set up, function and operate. Whilst the NCBP has given broad responsibilities, its powers actually derived or came from the individual mandates of a member-institutions and the residual power of the President in safeguarding the general welfare (Halos *et al.* 2004). The NCBP is not a stand alone agency rather it is attached to the DOST. Even though the NCBP is the highest regulatory body in the Philippines with respect to the introduction, use and

transfer of GMOs and PHES, its decisions are considered recommendatory. The NCBP's approval or disapproval of a biotechnology application for instance, is restricted to research and development (*i.e.* laboratory and field tests), technical aspects and scientific advice. Hence, the regulatory functions actually rely in effect on member regulatory agencies or Departments *i.e.* the DA, DENR and DOH. These set-ups were likewise cited during the development of the NBF presented by Halos *et al.* (2004). It is interesting to note however, that in spite of the lack of funding support and a very small Secretariat, the NCBP was able to deliver its basic mandates. This is one thing to look at from the perspective of a developing country such as the Philippines. The experience gained by the NCBP in terms of delivering results amidst insufficient funding reflects an effective operational biosafety management.

Conversely, ERMA is a prime body that is responsible for making decisions about importing, developing or manufacturing hazardous substances and new organisms; it is an independent regulatory authority. ERMA has two roles under the HSNO Act, they are the decision makers and they also monitor compliance and enforcement in view of the Act. One unique feature of ERMA as a stand alone agency is the partition of its functions into three inter-related elements *i.e.* the Authority which makes the decision, the Agency that provides executive support to the Authority and the Ngā Kaihautū Tikanga Taiao which act as the Authority's Maori Advisory Committee. The power of ERMA to make decisions and set the necessary conditions should a particular application be allowed for release made it different from the way the NCBP operates.

8.2.3 The issue of funding

The influence that a primary legislation can have and the difference it can make compared with a secondary legislation can be best explained by funding. Funding for the NCBP was supposed to be initially allocated from the DOST for its early operation and eventually be included in the General Appropriations Bill submitted to Congress each year. However, the funds were not consistently allocated, and the DOST has to find an alternative source of funds, *i.e.* utilising some of its Grants in Aid program intended for other R & D projects to support at least the Secretariat's operation. In contrast there is a different scenario in the case of ERMA; as a crown entity it gets direct funding consistently from the government to support the effective implementation of the HSNO Act.

8.2.4 Socio-economic considerations in decision-making

The debate between science-based vis-à-vis socio-economic considerations in doing risk assessment and making biosafety decisions is undoubtedly a major issue in both the Philippines and New Zealand. In the Philippines, the prevailing position is that socio-economic and cultural considerations are vital

components of biosafety decision-making and may be taken into account. Whilst socio-economic factors are considered in decision making, it was noted in the proposed NBF that its assessment should be conducted separately from risk assessment-science. This is where the Philippines and New Zealand have a commonality. In New Zealand, the debate is simplified between evidence-based and value-based decisions. However, the action taken in New Zealand is parallel to the way the Philippines sought to address it, *i.e.* to create a separate framework that will deal with the issues of social, cultural and ethical factors and leave risk assessment on a separate scientific risk assessment framework. The situation in the Philippines and New Zealand in a way supports the idea of integrating socio-economic considerations into biosafety decisions (Fransen *et al.* 2005).

8.2.5 Transparency and Public Participation

"Public participation and transparency in decision-making process are increasingly recognised as essential elements of good governance and sustainable development" (Fransen *et al.* 2005: 30). This statement arguably, is happening to a larger extent in the case of the Philippines and New Zealand; both are democratic societies and acknowledge the importance of transparency and public participation as vital components of a biosecurity or biosafety regimes. In the Philippines, the NCBP which is the highest regulatory body when it comes to biosafety has one social scientist and two community representatives out of its 10 governing members; most of whom have been appointed by the President of the Philippines since the creation of the NCBP in 1990. Moreover, there is community representation in the respective IBCs created by different institutions and organisations (under the NCBP guidelines and DA AO 8), that also make decisions before endorsing a project proposal and sending it to the NCBP or BPI for final assessment and approval. This in part reflects the way the community is valued as an integral component of biosafety decision making in the country.

In the case of New Zealand, in making decisions on approval for hazardous substances and new organisms, the Authority is mandated (under the HNSO Act) to take into account specific matters including the socio-economic, social and cultural well-being of all people and communities. In particular, the Authority also has to take into consideration Māori perspectives in decision-making. There is no direct community representative within the eight-members of the Authority, who are basically the people making decisions about whether or not hazardous substances or new organisms can be imported, developed or manufactured in New Zealand. However, the creation of the Authority's Māori Advisory Committee is a step towards recognizing Māori views and perspectives on matters relating to policy process and applications (ERMA 2004). The Authority also established an Ethics Advisory Panel that assists in its consideration of ethical and spiritual matters in decision making. In the IBSCs however, there is a Māori member and lay member of the community who sit in the Committee and represent the views of their community when making decisions on low-risk

containment application. The set up of public participation and representation in regulatory governance in the Philippines and New Zealand is obviously different in approach, but has the parallel goals of engaging the public and the community in the decision-making platform.

Furthermore, it is interesting to note that public participation occurred not just during the decision-making process but also during policy formulation. The development of the NBF and the public process that it went through which involved a series of multi-stakeholder, consultative workshops at the regional and national levels, were an example of how the Philippines engaged the public in the policy making process; they anchored the formulation of the NBF to the principle of transparency, participatory consultation and consensus building. The Philippines has a strong tradition of activism and grassroots movement (Fransen *et al.* 2005) and a dynamic social sector. Hence, it can be construed that the strength of the biosafety in the Philippines is the social process itself; it is being used as a counter balance to the complex scientific and legal issues inherent in biosafety governance. Public participation in the Philippines has brought other forms of specialised knowledge and experience (including indigenous knowledge and perceptions), besides scientific and technical perspectives, "that are also considered as relevant to policy formulation" (Glover & Keeley 2004: 47). In New Zealand, the Royal Commission on Genetic Modification's public consultation process which is considered as one of the most comprehensive public engagements ever conducted is a parallel illustration of the way the public can participate in shaping policy outcomes. Furthermore, it demonstrated "the usefulness of having several mutually enforcing streams of public consultation, and of making efforts to overcome cultural, temporal and geographic barriers to foster wide participation" (Pollak 2003).

8.2.6 Shared norms in Biosafety

There were some specific shared norms identified in biosafety in the Philippines and New Zealand in this study. First, both the Philippines and New Zealand adopt the case-by-case approach to approving or disapproving a particular GMO application intended for release into the environment. Second, the two countries shared a common practice of having a community representative in their respective IBCs so that the community has a voice during the evaluation of low-risk GMO applications.

8.3 Biosecurity Encompassing Biosafety in the Local Context

There is an interesting contrast between the Philippines and New Zealand's experiences in view of the idea of biosecurity encompassing biosafety. In the Philippines, the term biosecurity is a relatively new term for many. The system in the Philippines that can be attributed to biosecurity is the more traditional regulatory system focused on food safety, plant quarantine, animal quarantine, IPM, and through NIPAS, which are administered in different government departments and bureau or line

agencies. There is arguably a limited coordination and integration of these sectors in terms of addressing holistically the issues of biosecurity. The encompassing concept of biosecurity over biosafety (in view of the introduction and release of GMOs into the environment) is not happening in the Philippines; instead to some extent it is happening the other way around. The confusion on where to address the growing problem with IAS in the absence of a clear national policy to address it led to the inclusion of IAS under the proposed NBF. Currently and even before the creation of the proposed NBF, the Philippines is addressing the risks of introduction of IAS within the framework of biosafety under the guidelines set by NCBP on GMOs and PHES, whilst the protection and monitoring side of it is under the DENR-PAWB. The guidelines on GMOs and PHES reflected the recognition of the need to address concerns in these areas, however covering the issues of IAS (which pose a huge threat to the country's biodiversity) within the context of a biosafety framework showed that there is a clear absence of a biosecurity mechanism to address the issue within its context. On the other hand, in New Zealand, the encompassing nature of biosecurity over biosafety seems to be happening to some degree. The Ministry of Agriculture and Forestry which now looks after the whole-of-system approach to biosecurity performs tasks which are considered biosafety matters, *i.e.* being in-charge of the enforcement aspects of GMOs approved in containment or field release. Arguably however, there is still an artificial division within New Zealand between biosecurity and biosafety in terms of MAF doing the enforcement and ERMA doing the risk assessment of new organisms of which GMOs by definition (under the HSNO Act) are part. The MAF and ERMA may have different foci on dealing with new organisms but basically concerns involving new organisms fall within the biosecurity context and priority of New Zealand. In the case of New Zealand the tools for delivering biosecurity and biosafety are basically the same; it is just a matter of differentiating between the policy and risks assessments and the tools for delivering it. Biosecurity in New Zealand also evolved from a traditionally sectoral approach to biosecurity centred mainly on its primary production, to an expansion of including biodiversity; and the terrestrial and marine ecosystems; it transcended a more economic focus to a holistic and encompassing focus on economy, public health and the environment.

CHAPTER 9

CONCLUSION/IMPLICATIONS OF THE STUDY

9.1 Synthesized Concepts: Lessons from the Field

The evidence from the case studies generates synthesized concepts that can be considered and applied to future actions with the view to developing or improving the biosecurity and biosafety systems and frameworks not only in the countries of study but also in other advanced or developing countries. Potentially, it is also intended to inform policy making. The synthesized concepts presented in this study are lessons learned from the whole experience of undergoing this study and can be construed as a form of summary and general recommendations. As a way of presentation, the synthesized concepts are outlined in bullet points presented as an action agenda.

9.1.1 Biosecurity

- *Realising the need for a co-ordinated, enhanced and comprehensive approach to biosecurity.* Policies, regulations, strategies, and risk management frameworks should be comprehensively coordinated among agencies and the stakeholders involved.

- *Formulating appropriate policy and strategy.* A sound policy or biosecurity strategy serves as a platform for enabling biosecurity legislation; sets direction, goals and desired outcomes.

- *Enhancing capacity and capability in biosecurity risk assessment and management.* Strengthening human resource and developing expertise in assessing biosecurity risks; and improving or installing biosecurity facilities and infrastructure primarily to be able to trade equally in the international arena.

- *Strengthening the monitoring of compliance and stern enforcement mechanisms.* Monitoring of compliance and enforcement of the law at the pre-border, border and post-border are necessary elements of a successful biosecurity implementation.

- *Rationalising pest management strategies.* Setting best practises, standards and protocols provide for efficient and effective pest management.

- *Building and maintaining a good international reputation in biosecurity.* Fostering a good international reputation builds trust and confidence, and enhances trade relations.

9.1.2 Biosafety

- *Formulating and enacting primary legislation on biosafety.* A more permanent legislation is in itself an enabling mechanism for resource commitment, sustainable funding, and robust regulation.

- *Integrating socio-economic considerations in biosafety decision making.* Delineating and incorporating socio-economic, cultural, ethical, and spiritual considerations as part of decision-making, potentially under a separate framework from scientific risk assessment.

- *Building capacity and capability in biosafety.* The capacities of various sectors, policy makers, regulatory agencies, local government units, the research community and the general public involved in performing various tasks must be strengthened.

- *Making transparency and public participation an anchor of the biosafety regime.* There is a need for: (1) a coordinated and integrated system for promoting and facilitating public awareness of and education about biosafety; (2) a system that ensures correctness of the information and accountability; (3) scientists who can communicate the issues to all levels (primarily at the grassroots level).

- *Addressing the issue of access and ownership.* Ensuring that farmers have access to technology and are not displaced in their lands is of paramount concern and should be taken seriously.

- *Increasing understanding of biosafety as a multi-level and multi-sectoral issue.* Informed political leadership, top level government decision makers and policy makers as well as NGOs, POs, industry and other stakeholders would mean better policy and decision making.

9.2 Conclusion

In conclusion, this study has shown the complexity of systems, policies, legislation, regulations and cross-cutting issues that surround biosecurity and biosafety in the Philippines and New Zealand. The case studies highlight the challenges, issues and concerns that affect the biosecurity and biosafety systems from an advanced and a developing country perspective. In view of biosecurity, it clearly showed that the Philippines needs to shape a biosecurity policy or strategy that will serve as a blueprint in forming a stable biosecurity system in the country. This study has also found that there is limited

aspect of biosecurity being practised in the Philippines and responsibilities are scattered among different sectors. It is shown from this study that New Zealand has taken biosecurity management to the next level, *i.e.* from sectoral to a whole-of-system approach. The comparison between the two countries cemented the wide gap in terms of implementing a coordinated, enhanced and comprehensive biosecurity system; and the urgent need for a country like the Philippines to adopt or put up a similar system.

In view of biosafety, this study has shown the significance of having a primary legislation over secondary legislation in regulating biosafety. This means that a primary legislation facilitates enabling mechanism for resource commitment and robust regulation. The case studies highlighted the shared norms between the Philippines and New Zealand in terms of socio-economic, cultural and ethical considerations in biosafety decision-making; and in public participation. This suggests that advanced and developing countries are now realising the importance of these factors to the biosafety regulatory regime.

In terms of biosecurity encompassing biosafety in the local context, clearly such a concept is not (yet) present in the Philippines, whilst, to some extent it is happening in New Zealand. Therefore, unless steps are taken to make national policies better informed, enhance understanding of the nature and relevance of biosecurity, and set strategic and operational priorities, then there will be a continuing overlap between biosecurity and biosafety and the encompassing concept of biosecurity over biosafety will take a while to materialise in the local context.

9.3 Implications of the Study/Recommendations for Future Research

The results and findings of this study have implications for consideration in terms of practice and future research. This study has direct implications for countries like the Philippines and New Zealand that are setting biosecurity systems, policies and framework. Future research on the synthesized concepts provided above will pave the way for better understanding of the complex system of biosecurity and biosafety, and would provide a pragmatic resolution to outstanding biosecurity and biosafety issues and concerns.

9.4 Limitations of the Study

This study has identified certain limitations that can offer important insights for future research on the topic. Foremost, this study delved into a considerably broad and novel topic of biosecurity and biosafety and, as such it was like scratching the surface of these huge areas of research. Apparently,

the information and material related to biosecurity and biosafety systems and their interrelationship are scarce especially in the Philippines.

Second, this study used in-depth "elite" interviews as the primary data for analysing the phenomena but elite interviewing has its inherent limitations. Interviewing as many interviewees as possible across a range of disciplines status and levels in society would have better informed the cross-case analysis.

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APPENDIX A

MALACAÑANG
MANILA

BY THE PRESIDENT OF THE PHILIPPINES

EXECUTIVE ORDER NO.___

ESTABLISHING THE NATIONAL BIOSAFETY FRAMEWORK, PRESCRIBING GUIDELINES FOR ITS IMPLEMENTATION, STRENGTHENING THE NATIONAL COMMITTEE ON BIOSAFETY OF THE PHILIPPINES, AND FOR OTHER PURPOSES

WHEREAS, there is rapid expansion of the use of modern biotechnology not only for scientific research but also for products for commercial releases and purposes;

WHEREAS, there is a growing concern over modern biotechnology's potential impacts on the environment, particularly on biological diversity, on human health, and on social and cultural well-being;

WHEREAS, the Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity which the Philippines signed on 24 May 2000 entered into force on 11 September 2003;

WHEREAS, there is a need to establish and implement a National Biosafety Framework that would respond to the challenges presented by modern biotechnology;

WHEREAS, the National Committee on Biosafety of the Philippines (NCBP) has played, since 1987, a pioneering and important role in developing and establishing the current biosafety system, and that it needs to be strengthened so that it can better respond to these challenges.

NOW, THEREFORE, I, GLORIA MACAPAGAL-ARROYO, President of the Philippines, by virtue of the powers vested in me by law, do hereby order:

SECTION 1. Adoption and Operationalization of the National Biosafety Framework. The National Biosafety Framework (NBF) for the Philippines, attached hereto as Annex A, is hereby adopted.

SECTION 2. Scope and Objectives. The NBF shall have the following scope and objectives:

*2.1 **Scope.*** The NBF shall apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making biosafety decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles.

The NCBP and concerned departments and agencies may apply, when allowed by law, the principles, mechanisms and processes developed and implemented under the NBF to similar problems such as addressing the issue of exotic species and invasive alien species. Where appropriate, they may adopt the administrative and decision-making systems established in this Order.

*2.2 **Objectives.*** The NBF shall have the following objectives:

2.2.1 Establish a science-based determination of biosafety to ensure the safe and responsible use of modern biotechnology so that the Philippines and its citizens can benefit from its application while avoiding or minimizing the risks associated with it;

2.2.2 Establish a decision-making system on the application of products of modern biotechnology that is efficient, predictable, effective, balanced, culturally appropriate, ethical, transparent and participatory; and,

2.2.3 Serve as guidelines for implementing international obligations on biosafety.

Section 3. Administrative Framework and Decision-Making processes. In making biosafety decisions, the administrative system and decision-making processes established in the NBF shall be complied with.

Section 4. Strengthening the National Committee on Biosafety of the Philippines (NCBP). The NCBP is hereby strengthened. Its mandate, functions, composition and organization are set forth in the NBF

Section 5. General Mandate on Departments, Offices and Agencies. All departments and agencies shall exercise jurisdiction and all other powers that they have been conferred with under existing laws. They shall be guided by the NBF and coordinate with each other in exercising such powers.

Section 6. Funding. The DOST, DENR, DA, and DOH shall allocate funds from their present budgets to implement the NBF, including to support the operations of the NCBP and its Secretariat for 2004 and 2005. Starting 2006 and thereafter, the funding requirements shall be included in the General Appropriations Bill submitted to Congress.

These concerned departments, on an annual or other periodic basis, shall enter into agreement on the sharing of financial and technical resource to support the NCBP and its Secretariat.

Section 7. Transition. The NCBP and its present members shall continue to exercise their present functions under EO 430 until such time that it has completely reorganized under the NBF, which reorganization shall be completed within one year of its effectivity.

All members of the NCBP to be appointed by the President, as required by the NBF, shall assume their positions within the same period of time.

Section 8. Repealing and Amending Clause. All orders, rules and regulations or parts thereof which are inconsistent with any of the provisions of this Order are hereby repealed or amended accordingly.

SECTION 9. Effectivity. This Order shall take effect immediately. **DONE**, in the City of Manila, this ____ day of _____ in the year of our Lord two thousand and four.

GLORIA MACAPAGAL-ARROYO

By the President:

Executive Secretary

NATIONAL BIOSAFETY FRAMEWORK FOR THE PHILIPPINES

SECTION 1. CONSTITUTIONAL POLICIES

In implementing the National Biosafety Framework (NBF), the following state policies mandated by the 1987 Constitution shall guide the concerned government department and agencies:

1.1 Right to Health. The State shall protect and promote the right to health of the people and instill health consciousness among them (Article II, Section 15);

1.2 Right to a Healthy Environment. The State shall protect and advance the right of the people to a balanced and healthful ecology in accord with the rhythm and harmony of nature (Article II, Section 16);

1.3 Priority to Science. The State shall give priority to education, science and technology, arts, culture, and sports to foster patriotism and nationalism, accelerate social progress, and promote total human liberation and development (Article II, Section 17);

1.4 Role of the Private Sector. The State recognizes the indispensable role of the private sector, encourages private enterprise, and provides incentives to needed investments (Article II, Section 20);

1.5 Rural Development. The State shall promote comprehensive rural development and agrarian reform (Article II, Section 21) and shall provide support to agriculture through appropriate technology and research, and adequate financial, production, marketing, and other support services (Article XIII, Section 5);

1.6 Right of Indigenous Peoples and Communities. The State recognizes and promotes the rights of indigenous cultural communities within the framework of national unity and development (Article II, Section 22). The State, subject to the provisions of this Constitution and national development policies and programs, shall protect the rights of indigenous cultural communities to their ancestral lands to ensure their economic, social, and cultural well-being (Article XIII, Section 5);

1.7 Right to Information. Subject to reasonable conditions prescribed by law, the State adopts and implements a policy of full public disclosure of all its transactions involving public interest (Article II, Section 28);

1.8 Local Autonomy. The territorial and political subdivisions shall enjoy local autonomy (Article 10, Section 2);

1.9 Right to Participation. The right of the people and their organizations to effective and reasonable participation at all levels of social, political, and economic decision-making shall not be abridged. The State shall, by law, facilitate the establishment of adequate consultation mechanisms (Article XIII, Section 16);

1.10 Science and Technology. Science and technology are essential for national development and progress. The State shall give priority to research and development, invention, innovation, and their utilization; and to science and technology education, training, and services. It shall support indigenous, appropriate, and self-reliant scientific and technological capabilities, and their application to the country's productive systems and national life. The State shall regulate the transfer and promote the adaptation of technology from all sources for the national benefit. It shall encourage the widest participation of private groups, local governments, and community-based organizations in the generation and utilization of science and technology (Article XIV, Sections 10 and 12); and,

1.11 Consumer Protection. The State shall protect consumers from trade malpractice and substandard and hazardous products (Article. XVI, Section. 9).

SECTION 2. PRINCIPLES

The following principles, based on national and international law, shall apply in a mutually supportive manner to the implementation of the NBF:

2.1 Policy on Modern Biotechnology. The NBF shall be implemented in the context of the overall policy of the Philippines on modern biotechnology, to wit: The State shall promote the safe and responsible use of modern biotechnology and its products as one of the several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development;

2.2 Policy on Sustainable Development. The overall policy of the Philippines on sustainable development, as laid down in Philippine Agenda 21, shall equally guide the implementation of the NBF;

2.3 A Balanced Approach. A balanced approach, which recognizes both the potential benefits and risks, shall guide the implementation of the NBF. This shall be based on recognition that modern biotechnology has significant potential for human well-being if developed and used with adequate safety measures for the environment and human health. Such approach recognizes both the potential benefits and risks of modern biotechnology to human health, agricultural productivity, food security, the livelihoods of the poor, biological diversity and the environment;

2.4 A Scientific Approach. The implementation of the NBF shall be based on the best available science and knowledge. Such science and knowledge must be of the highest quality, multi-disciplinary, peer-reviewed, and consistent with international standards as they evolve;

2.5 Socio-economic, Cultural, and Ethical Considerations. The socio-economic, ethical and cultural benefits and risks, of modern biotechnology to the Philippines and its citizens, and in particular on small farmers, indigenous peoples, women, small and medium enterprises and the domestic scientific community, shall be taken into account in implementing the NBF;

2.6 Using Precaution. In accordance with Principle 15 of the Rio Declaration of 1992 and the relevant provisions of the Cartagena Protocol on Biosafety, in particular Articles 1, 10 (par. 6) and 11 (par. 8), the precautionary approach shall guide biosafety decisions. The principles and elements of this approach shall be implemented through the decision-making system in the NBF;

2.7 Transparency and Public Participation. Decision taken under the NBF shall be arrived at in a transparent and participatory manner. Biosafety issues are best handled with the participation of all relevant stakeholders and organizations. They shall have appropriate access to information and the opportunity to participate in biosafety decision-making processes;

2.8 Consensus Building. In making biosafety decisions, all concerned government departments and agencies shall exert all efforts to find consensus among all relevant stakeholders using well-accepted methods such as negotiation, mediation, and other appropriate dispute resolution processes. Such consensus, to be achieved in a transparent and participatory manner, shall be based on the best available science and knowledge and shall not compromise public safety and welfare;

2.9 Principle of Subsidiarity. As provided by law and where competence exists, all levels of government, including local government units, shall participate in implementing the NBF;

2.10 Availability of Remedies. Effective access to judicial and administrative proceedings, including redress and remedy, shall be available in accordance with Philippine law;

2.11 International Obligations and Cooperation. In accordance with international law, the NBF shall be implemented in a manner consistent with and mutually supportive to the international obligations of the Philippines, in particular its obligations under international trade and environmental law. Multilateral, regional and bilateral cooperation in implementing the NBF, in particular its sections on capacity building and financial resources, shall be encouraged;

2.12 Efficient Administration and Timely Decision Making . The NBF decision making process must be conducted in an efficient, coordinated, effective, predictable, cost-effective and timely manner. Undue delay shall be avoided without compromising transparency, public participation, public safety, and public welfare; and,

2.13 Public interest and welfare. In cases of conflict in applying these principles, the principle of protecting public interest and welfare shall always prevail. No section or provision in this Framework shall be construed as to limit the legal authority and mandate of heads of departments and agencies to consider the national interest and public welfare in making biosafety decisions.

SECTION 3. SCOPE, OBJECTIVES AND DEFINITIONS

3.1 Scope. The NBF shall apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles. The NCBP and concerned departments and agencies may apply, when allowed by law, the principles, mechanisms and processes developed and implemented under the NBF to similar problems such as addressing the issue of exotic species and invasive alien species. Where appropriate, they may adopt the administrative and decision-making systems established in this Framework.

3.2 Objectives . The NBF shall have the following objectives: 3.2.1 Establish a science-based determination of biosafety to ensure the safe and responsible use of modern biotechnology so that the Philippines and its citizens can benefit from its application while avoiding or minimizing the risks associated with it;

3.2.2 Establish a decision-making system on the application of products of modern biotechnology that is efficient, predictable, effective, balanced, culturally-appropriate, ethical, transparent and participatory; and,

3.2.3 Serve as guidelines for implementing international obligations on biosafety.

3.3 Definitions. For purposes of this framework, the following terms shall mean:

3.3.1 "Biosafety" is a condition in which the probability from harm, injury and damage resulting from the intentional and unintentional introduction and/or use of a regulated article is within acceptable and manageable levels;

3.3.2 "Biosafety Clearing house" is an information exchange mechanism established by the Cartagena Protocol on Biosafety to assist parties in the implementation of its provisions and to facilitate sharing and exchange of scientific, technical, environmental and legal information on, and experience with, regulated articles;

3.3.3 "Biosafety decisions" apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles; 3.3.4 "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

3.3.5 "Genetically modified organism" also refers to "living modified organism" under the Cartagena Protocol on Biosafety and refers to any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

3.3.6 "Handling and Use" means the process by which regulated articles are moved, carried, transported, delivered, stored or worked with;

3.3.7 "Hazard" refers to traits inherent to or activities of a regulated article that may cause harm to human or animal health or to the environment;

3.3.8 "Management" means measures adopted after the release of regulated articles to ensure their safe use and, in cases of commercial release, shall also include product monitoring and product identification;

3.3.9 "Modern biotechnology" means the application of: a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) or direct injection of nucleic acid into cells or organelles; or b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding or selection;

3.3.10 "Product identification" refers to information on the presence of a regulated article in a particular product, as implemented by concerned departments and agencies through import and export documents, unique identification system, or similar applicable approaches such as product labeling;

3.3.11 "Product Monitoring" refers to any post-commercialization measure that provides data on the fate and effects of the regulated article, in order to confirm compliance with regulatory requirements, collect information necessary for controlling and managing potentially adverse public health or environmental situations, assess environmental quality and detect unexpected or potentially damaging effects on human and animal health and the environment. Product monitoring helps reduce uncertainty remaining from risk assessment, confirm conclusions with additional data and provide informational feedback on system status or conditions;

3.3.12 "Regulated article" refers to a genetically modified organism and its products;
3.3.13 "Risk" refers to the combination of the likelihood that an adverse consequence of a biohazardous activity or trait will occur and the magnitude of such a consequence;

3.3.14 "Risk assessment" refers to the procedure that identifies, evaluates and predicts the occurrence of possible hazards to human and animal health and the environment and designs mitigating measures to avert or minimize these hazards;

3.3.15 "Risk management" refers to appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment including those conditions imposed by concerned departments or agencies;

3.3.16 "Transboundary movement" means the movement of a regulated article from another country to the Philippines; and,

3.3.17 "Transformation event" means one instance of entry, stable integration and expression of an introduced gene into a cell which then develops into a functional organism expressing the introduced gene.

SECTION 4. ADMINISTRATIVE FRAMEWORK

The administrative mechanism for biosafety decisions shall be as follows: (a) National scientific and technical biosafety standards and standards on methods and procedures for ensuring biosafety in the country, shall be set by the NCBP consistent with existing laws;

(b) Basic policies on addressing public interests on biosafety shall be developed by the NCBP, provided the same are consistent with law and/or if such policies are found insufficiently addressed in existing mandates and regulations of pertinent agencies;

(c) Member-agencies of the NCBP shall continue to perform their regulatory functions in accordance with their legal mandates, provided that their policies and programs relating to biosafety shall be discussed in the NCBP for purposes of harmonization with other agencies' functions;

(d) Other concerned agencies shall coordinate with NCBP on matters that may affect biosafety decisions as provided in Sections 4.7 to 4.14;

(e) Administrative functions required under the Cartagena Protocol on Biosafety shall be performed by agencies as provided in Section 4.14 and 4.15; and,

(f) The role of stakeholders and the general public shall be recognized and taken into account as provided in Sections 6 and 7.

4.1 ***Mandate of the National Committee o n Biosafety of the Philippines (NCBP).*** The NCBP shall be the lead body to coordinate and harmonize interagency and multi-sector efforts to develop biosafety policies in the country (where such are not already stipulated by law) and set scientific, technical and procedural standards on actions by agencies and other sectors to promote biosafety in the Philippines; oversee the implementation of the NBF; act as a clearing house for biosafety matters; and coordinate and harmonize the efforts of all concerned agencies and departments in this regard.

4.2 ***Composition of the NCBP*** . The NCBP shall be composed of the following:

4.2.1. The Secretaries of the Departments of Science and Technology, Agriculture, Health, Environment and Natural Resources, Foreign Affairs, Trade and Industry, and Interior and Local Governments or their designated representatives. The DOST Secretary shall be the permanent Chair;

4.2.2 A representative of civil society to be recommended by the Civil Society Counterpart of the Philippine Council on Sustainable Development (PCSD) to the NCBP and appointed by the President, serving for a term of three (3) years, renewable for another term;

4.2.3 A community representative from the farmers, fisherfolk and indigenous sector appointed by the President from a list submitted by nationally recognized sectoral organizations, serving for a term of three (3) years, renewable for another term;

4.2.4 A representative from industry appointed by the President from a list submitted by the Secretary of Trade and Industry, serving for a term of three (3) years, renewable for another term; and,

4.2.5 A biological scientist, physical scientist, environmental scientist, health scientist, and social scientist to be endorsed by the DOST Secretary upon the recommendation of recognized professional and collegial bodies such as the National Academy of Science and Technology (NAST) and the Philippine Social Science Council (PSSC), and appointed by the President, serving for a term of three (3) years, renewable for another term.

4.3 NCBP Executive Committee and Technical Working Groups . The NCBP may create an Executive Committee and Technical Working Groups as it deems necessary and appropriate.

4.4 Meetings of the NCBP . The NCBP shall meet regularly as it deems fit and shall formulate its standards for making decisions.

4.5 NCBP Secretariat . The NCBP shall create a Secretariat that shall be based in the DOST. All other concerned agencies shall participate in the functions of the Secretariat.

4.6 Powers and Functions of the NCBP . As the lead body in implementing the NBF, the NCBP shall have the following powers and functions:

4.6.1 Biosafety Policy Functions

4.6.1.1 Assist concerned departments and agencies in formulating, reviewing, or amending their respective policies, measures and guidelines on biosafety;

4.6.1.2 Hold public deliberations on proposed national policies, guidelines, and other biosafety issues;

4.6.1.3 Provide assistance in the formulation, amendment of pertinent laws, rules and regulations;

4.6.1.4 In coordination with concerned departments and agencies and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, shall take the lead in periodically reviewing the NBF;

4.6.1.5 Issue detailed guidelines on the conduct of socio-economic impact evaluation of biosafety decisions; and,

4.6.1.6 Propose to Congress necessary and appropriate legislation.

4.6.2 Accountability Functions

4.6.2.1 Monitor the implementation of the NBF by concerned departments and agencies;

4.6.2.2 Ensure coordination among competent national authorities that have shared mandates;

4.6.2.3 Ensure that NCBP guidelines, and the principles and processes established in this Framework are complied with by concerned departments and agencies; and,

4.6.2.4 Review procedures for accountability in biosafety decision-making by competent national authorities, with particular emphasis on ensuring independence and impartiality in such decisions.

4.6.3 Scientific Functions

4.6.3.1 Facilitate the study and evaluation of biosafety research and control and minimize the concomitant risks and hazards associated with the deliberate release of regulated articles in the environment;

4.6.3.2 Identify and evaluate potential hazards involved in modern biotechnological experiments or the introduction of regulated articles and recommend measures to minimize risks;

4.6.3.3 Recommend the development and promotion of research programs to establish risk assessment protocols and assessment of long-term environmental effects of regulated articles;

4.6.3.4 Develop working arrangements with the government quarantine services and institutions in the evaluation, monitoring, and review of projects vis-à-vis adherence to national policies and guidelines on biosafety;

4.6.3.5 Review and develop guidelines in the risk assessment of regulated articles for contained use;
4.6.3.6 Assist other agencies in developing risk assessment guidelines and procedures of regulated articles for field trials and commercial release;

4.6.3.7 Review the appointment of the members of the Institutional Biosafety Committees created by institutions engaged in activities involving regulated articles, upon recommendation by their respective heads of institutions;

4.6.3.8 Publish the results of internal deliberations and agency reviews of the NCBP;

4.6.3.9 Hold discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the purposes/objectives of the proposed genetic modification products and/or services; and,

4.6.3.10 Perform such functions as may be requested by concerned departments and agencies.

4.6.4 Capacity Building Functions

4.6.4.1 Assist in the development of technical expertise, facilities, and other resources for quarantine services and risk assessments; and,

4.6.4.2 Take the lead in developing and implementing a national capacity-building program for biosafety.

4.7 ***Mandate of the Department of Science and Technology.*** The Department of Science and Technology (DOST), as the premiere science and technology body in the country, shall take the lead in ensuring that the best available science is utilized and applied in adopting biosafety policies, measures and guidelines, and in making biosafety decisions. The DOST shall ensure that such policies, measures, guidelines and decisions are made on the basis of scientific information that is of the highest quality, multi-disciplinary, peer-reviewed, and consistent with international standards as they evolve. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws.

4.8 Mandate of the Department of Agriculture . As the principal agency of the Philippine government responsible for the promotion of agricultural development growth, rural development so as to ensure

food security and contribute to poverty alleviation, the Department of Agriculture shall take the lead in addressing biosafety issues related to the country's agricultural productivity and food security. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws.

4.9 ***Mandate of the Department of Environment and Natural Resources***. As the primary government agency responsible for the conservation, management, development and proper use of the country's environment and natural resources, the Department of Environment and Natural Resources (DENR) shall ensure that environmental assessments are done and impacts identified in biosafety decisions. It shall also take the lead in evaluating and monitoring regulated articles intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources.

4.10 Mandate of the Department of Health. The Department of Health (DOH), as the principal authority on health, shall formulate guidelines in assessing the health impacts posed by modern biotechnology and its applications. The DOH shall also require, review and evaluate results of environmental health impact assessments related to modern biotechnology and its applications. In coordination with other concerned departments and agencies, it shall exercise such jurisdiction and other powers that it has been conferred with under existing laws.

4.11 ***Mandate of the National Commission on Indigenous Peoples***. The National Commission on Indigenous Peoples (NCIP) shall take the lead in ensuring that the rights of indigenous peoples and communities are recognized and protected in all biosafety decisions made which affect them. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided in Sections 6 and 7 of the NBF, the NCIP shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. In particular, the NCIP shall ensure that free and prior informed consent by indigenous peoples and communities has been given to the introduction and/or use of regulated articles within the ancestral lands and domains of indigenous peoples and communities.

4.12 Local Government Units. The autonomy of local government units (LGUs) is recognized under existing laws and regulations. In this regard, the DILG, in coordination with appropriate agencies, shall encourage and support the active participation of LGUs in capacity building, decision making, program planning, and implementation related to biosafety.

4.13 Mandate of Other Departments and Agencies. In coordination with other concerned departments and agencies, and consistent with the requirements of transparency and public participation as provided

in Sections 6 and 7 of the NBF, all other departments and agencies shall exercise such jurisdiction and other powers that it has been conferred with under existing laws. In particular, the following departments and agencies shall participate in biosafety decision making, where appropriate: the Department of Foreign Affairs in promoting and protecting Philippine interests on biosafety in bilateral, regional and multilateral forums; the Department of Trade and Industry in relation to biosafety decisions which have an impact on trade, intellectual property rights, investments and consumer welfare and protection.

4.14 Focal Point and Competent National Authorities.

4.14.1 For purposes of Article 19 of the Cartagena Protocol on Biosafety, the national focal point responsible for liaison with the Secretariat shall be the Department of Foreign Affairs. The competent national authorities, responsible for performing the administrative functions required by the Protocol, shall be, depending on the particular genetically modified organisms in question, the following:

4.14.1.1 The Department of Agriculture, for biosafety decisions, when covered by the Protocol, concerning plants and plant products derived from modern biotechnology, fisheries and other aquatic resources, domesticated animals and biological products used for animal husbandry or veterinary purposes and biological agents used for biocontrol;

4.14.1.2 The Department of Science and Technology, for biosafety decisions concerning research and development, when covered by the Protocol;

4.14.1.3 The Department of Health, for biosafety decisions concerning pharmaceuticals for humans that are not explicitly excluded under Article 5 of the Protocol, i.e. pharmaceuticals which are not addressed by other relevant international agreements or organizations; and,

4.14.1.4 The Department of Environment and Natural Resources, for biosafety decisions covered by the Protocol that concern regulated organisms intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources, and applications of modern biotechnology with potential impact on the conservation and sustainable use of biodiversity.

4.14.2 The national focal point and the competent authorities listed above shall, as appropriate, coordinate with the NCBP in accordance with its mandate under Section 4.1. For genetically modified organisms not falling under the jurisdiction of the competent authorities enumerated above, the NCBP shall designate the appropriate agency that shall act as such authority.

4.15 Biosafety Clearing House. Concerned government departments and agencies shall utilize the Biosafety Clearing House (BCH) of the Cartagena Protocol on Biosafety in developing and adopting biosafety policies, guidelines, and measures and in making biosafety decisions. The NCBP Secretariat shall serve as the focal point for the BCH in coordination with the DENR-PAWB serving as the focal point for the Clearing House Mechanism (CHM) of the Convention on Biological Diversity.

4.16 Role of Stakeholders and t he Public . The role of relevant stakeholders and the public in biosafety decisions is provided for in Sections 6 and 7 of this Framework.

SECTION 5. DECISION-MAKING PROCESSES

Biosafety decisions shall be made in accordance with existing laws and the following guidelines:

5.1 Standard of Precaution. In accordance with Article 10 (par. 6) and Article 11 (par. 8) of the Cartagena Protocol on Biosafety, lack of scientific certainty or consensus due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a genetically modified organism on the environment, particularly on the conservation and sustainable use of biological diversity, and on human health, shall not prevent concerned government departments and agencies from taking the appropriate decision to avoid or minimize such potential adverse effects. In such cases, concerned government department and agencies shall take the necessary action to protect public interest and welfare.

5.2 Risk Assessment . Risk assessment (RA) shall be mandatory and central in making biosafety decisions. It shall identify and evaluate the risks to human health and the environment, and if applicable, to animal health.

5.2.1 Principles of Risk Assessment . The following principles shall be followed when performing a RA to determine whether a regulated article poses significant risks to human health and the environment:

5.2.1.1 The RA shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information. The expert advice of and guidelines developed by, relevant international organizations, including intergovernmental bodies, and regulatory authorities of countries with significant experience in the regulatory supervision of the regulated article shall be taken into account in the conduct of risk assessment;

5.2.1.2 Lack of scientific knowledge or scientific consensus shall not be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;

5.2.1.3 The identified characteristics of a regulated article and its use which have the potential to pose significant risks to human health and the environment shall be compared to those presented by the nonmodified organism from which it is derived and its use under the same conditions;

5.2.1.4 The RA shall be carried out case-by-case and on the basis of transformation event. The required information may vary in nature and level of detail from case to case depending on the regulated article concerned, its intended use and the receiving environment; and,

5.2.1.5 If new information on the regulated article and its effects on human health and the environment becomes available, and such information is relevant and significant, the RA shall be readdressed to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly.

5.2.2 ***Risk Assessment Guidelines.*** The conduct of RA by concerned departments and agencies shall be in accordance with the policies and standards on RA issued by the NCBP. Annex III of the Cartagena Protocol shall also guide RA. As appropriate, such department and agencies may issue their own respective administrative issuances establishing the appropriate RA under their particular jurisdictions.

5.3 Role of Environmental Impact Assessment . The application of the EIA System to biosafety decisions shall be determined by concerned departments and agencies subject to the requirements of law and the standards set by the NCBP. Where applicable and under the coordination of the NCBP, concerned departments and agencies shall issue joint guidelines on the matter.

5.4 ***Socio-economic, Ethical, Cultural and Other Considerations.*** Consistent with Article 26 of the Cartagena Protocol, concerned government departments and agencies may take into account socio-economic considerations arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

The NCBP shall issue guidelines relating to the conduct of social, economic, ethical, cultural and other assessments, as appropriate , particularly prior to decisions to commercialize products of modern biotechnology. These assessments shall be conducted separately from risk assessment and in a transparent, participatory and rigorous manner.

5.5 ***Decisions under the Cartagena Protocol*** . For decisions required under the Cartagena Protocol on Biosafety, the competent national authorities identified may choose to adopt the procedures of the Advance Informed Agreement as provided in Articles 7, 8, 9, 10, 11, 12 and 13 of the Protocol or issue their own respective rules and regulations provided that such rules and regulations are consistent with the Protocol. In all cases, decisions under this Framework shall fall within those timeframes required under the Cartagena Protocol. As provided however in the Protocol, failure to comply with such timeframes shall not imply consent to an intentional transboundary movement of genetically modified organisms covered under the Protocol.

5.6 Monitoring and Enforcement. All concerned departments and agencies shall monitor compliance to the conditions attached to approvals and authorizations, especially on risk management, in a manner that is transparent, and in coordination with other agencies, including LGUs, and other stakeholders. It shall also include monitoring for impacts, whether anticipated or not, of the introduced product on environment and health.

SECTION 6. ACCESS TO INFORMATION

The right of the public and the relevant stakeholders to information related to biosafety decisions is recognized and shall always be respected in accordance with the following guidelines.

6.1 Information on Applications . Concerned departments and agencies shall, subject to reasonable limitations to protect confidential information as provided below, disclose all information on such applications in a prompt and timely manner. Such departments and agencies may require applicants to provide the information directly to concerned stakeholders.

6.2 Confidential Information. In all applications for approvals, whether domestic or foreign, concerned departments and agencies shall ensure that it has procedures and regulations to determine and protect confidential information; Provided, however, that the concerned agencies may refuse declaring the confidentiality of such information if the public interest in disclosure outweighs the prejudice that the disclosure would cause to any entity.

6.3 Information on Biosafety Decisions. The public and stakeholders shall have access to all biosafety decisions and the information on which they are based, subject to limitations set in Section 6.2 of this Framework. Such decisions shall summarize the application, the results of the risk assessment, and other relevant assessments done, the public participation process followed, and the basis for approval or denial of the application.

6.4 Information on Risk Management, Product Monitoring, and Product Identification. All relevant stakeholders shall have access to information related to risk management and product monitoring. Information on product identification shall be provided to the general public.

SECTION 7. PUBLIC PARTICIPATION The concerned government departments and agencies, in developing and adopting biosafety policies, guidelines and measures and in making biosafety decisions, shall promote, facilitate, and conduct public awareness, education, and meaningful participation. They shall incorporate into their respective administrative issuances and processes best practices and mechanisms on public participation in accordance with the following guidelines:

7.1 *Scope of Public Participation.* Public participation shall apply to all stages of the biosafety decision-making process from the time the application is received. For applications on biotechnology activities related to research and development, limited primarily for contained use, notice of such application through the NCBP shall be sufficient unless public interest and welfare requires otherwise.

7.2 *Minimum Requirements of Public Participation.* In conducting public participation processes, the following minimum requirements shall be followed:

7.2.1 Notice to all concerned stakeholders, in a language understood by them and through media to which they have access. Such notice must be adequate, timely, and effective and posted prominently in public places in the areas affected, and in the case of field trials and commercial releases, in both national and local print and broadcast media. In all cases, such notices must be posted electronically in the internet;

7.2.2 Adequate and reasonable time frames for public participation procedures. Such procedures should allow relevant stakeholders to understand and analyze the benefits and risks, consult with independent experts, and make timely interventions. Concerned departments and agencies shall include in their appropriate rules and regulations specific time frames for their respective public participation processes, including setting a minimum time frame as may be appropriate;

7.2.3 Public consultations , as a way to secure wide input into the decisions that are to be made. These could include formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy about the proposed activities. Public consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their appropriate rules and regulations the stages when public consultations are appropriate, the specific time frames for such consultations, and the circumstances

when formal hearings will be required, including guidelines to ensure orderly proceedings. The networks of agricultural and fisheries councils, indigenous peoples and community-based organizations in affected areas shall be utilized;

7.2.4 Written submissions . Procedures for public participation shall include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any positions, comments, information, analyses or opinions. Concerned departments and agencies shall include in their appropriate rules and regulations the stages when and the process to be followed for submitting written comments; and,

7.2.5 Consideration of public concerns in the decision -making phase following consultation and submission of written comments. Public concerns as reflected through the procedures for public participation shall be considered in making the decision. The public must be informed of the final decision promptly, have access to the decision, and shall be provided with the reasons and considerations resulting in the decision, upon request.

SECTION 8. CAPACITY BUILDING AND FINANCIAL RESOURCES

Implementing the NBF requires the design, adoption and implementation of a capacity-building program supported by adequate financial resources. The following considerations shall be taken into account in developing such a program:

8.1 Need for Capacity Building. To ensure the proper implementation of the NBF, the capacities of various sectors: policy-makers, regulatory agencies, local government units, research community and the general public involved in performing various tasks must be strengthened;

(a) Policy makers must be made aware of issues and provided with sufficient and most current information on biosafety for the enactment of appropriate policies, regulations and programs;

(b) Expertise and appropriate facilities in regulatory agencies must be developed for the safety assessment of regulated articles, harmonization of regulatory policies and procedures and monitoring compliance and outcomes to biosafety regulations;

(c) The research community must be supported to enable them to address the safety issues of regulated articles; and,

(d) The general public must be made aware of issues, provided with the correct information and enabled to participate in the biosafety decision-making process. The capacity of environmental and developmental non-government organizations, people's organizations, professional organizations, including industry and other concerned entities to assist in this capacity-building program shall be enhanced. Agencies involved in implementing the NBF should undertake programs to achieve the above objectives.

8.2 Areas for Capacity Building. Capacity building in all areas relevant to biosafety and biosafety-decision making is necessary, and particularly in the following: in conducting risk assessment; in undertaking social, economic, cultural, ethical and other assessments; and, in implementing transparent and effective public participation procedures.

8.3 Designing and Implementing a Capacity -Building Program. In coordination with other concerned government department and agencies, and with the participation of all relevant stakeholders, the NCBP shall take the lead in developing and implementing multi-agency and multi-sector capacity-building programs that are needed for the effective implementation of the NBF. The basis of such programs shall be a capability needs assessment undertaken by each concerned department and agency and by the relevant stakeholders.

8.4 Financial Resources. The DOST, DENR, DA, and DOH shall allocate from their present budgets such amount as may be necessary to implement the NBF, including to support the operations of the NCBP and its Secretariat. Thereafter, the funding requirements shall be included in the General Appropriations Bill submitted to Congress. These concerned departments, on an annual or other periodic basis, shall enter into agreement on the sharing of financial and technical resource to support the NCBP and its Secretariat.

SECTION 9. REMEDIES

In cases of violations of laws, rules, and regulations related to biosafety, the following remedies shall apply:

9.1 *Administrative Remedies.* The concerned departments and agencies shall ensure, in accordance with law, that the right of appeal and other administrative remedies are available to applicants and relevant stakeholders in biosafety decisions.

9.2 *Criminal Liability* . Natural or juridical persons committing offenses in violation of existing laws shall be prosecuted and penalized in accordance with such laws.

9.3 ***Civil Liability*** . Philippine laws on liability and compensation for damages resulting injuries committed on persons shall apply in accordance with such laws. Concerned departments or agencies shall study the feasibility of requiring such instruments as indemnification bonds.

9.4 International Law. International legal norms on liability and compensation, including those developed and adopted under the Cartagena Protocol on Biosafety, shall likewise apply.

9.5 Review of Remedies. Recognizing the current gaps in the law on remedies related to biosafety, the NCBP shall, as a matter of priority, review the existing laws and recommend to Congress the appropriate legislation.

SECTION 10. REVIEW

The NBF shall be reviewed periodically to identify gaps and lessons learned from its implementation and to incorporate new information that may lead to its improvement. Such review shall be conducted in five year intervals unless circumstances, such as emergencies or new developments in the science and technology, require an earlier review.

10.1 Review Process. The review shall be initiated by the NCBP and shall involve concerned departments and agencies. Public consultations, in accordance with Section 6, shall be undertaken whenever substantive changes are proposed to the Framework.

10.2 Process of Delisting . Delisting of regulated articles shall rest on the regulatory agencies, subject to guidelines set under the NCBP process. The NCBP shall initiate a study on the feasibility of a delisting procedure for regulated articles.

10.3 Legislation . Lessons learned from implementing the Framework shall be documented and, at an appropriate time, conveyed to Congress for purposes of developing, drafting and adopting legislation on biosafety.

APPENDIX B

GENERAL INTERVIEW GUIDE QUESTIONS

1. What can you say about the biosecurity/biosafety system in the country?

2. What framework for addressing biosecurity/biosafety issues and concerns does the country follow?

3. Do you agree that biosecurity should encompass biosafety? To what extent do you think should biosecurity encompass biosafety?

4. What is your comment to the international/regional harmonisation of biosecurity efforts?

5. Do you agree that there is need for a coordinated and/or unified approach to handling the issues of biosecurity and biosafety? How do you think the Philippines/New Zealand should address the issue of biosecurity in relation to biosafety?

6. What is you comment in terms of capacity and capability of the country in implementing biosecurity/biosafety measures?

7. To what extent do you think the Philippines/New Zealand accommodates transparency and public participation in the policy and decision making process in terms of biosecurity? In terms of biosafety?

8. How do you think cultural, ethical and spiritual values could be incorporated in the risks assessment mechanism?

9. What is your comment on the use of the Precautionary Principle in dealing with the issues on biosecurity/biosafety?

10. In terms of risk assessment, where do you stand: strictly science-based vs. consideration of socio-economic issues/concerns?

APPENDIX C

LIST OF MAJOR DOCUMENTS EXAMINED

In the Philippines:

1. Developing the National Biosafety Framework (NBF) for the Philippines, 2004.

2. Proceedings: National Workshop in Developing the NBF for the Philippines, 2-3 March 2004.

3. Proceedings: Mindanao Regional Workshop in Developing the NBF for the Philippines, 5-6 January 2004.

4. Proceedings: Luzon Regional Workshop in Developing the NBF for the Philippines, 8-9 January 2004.

5. Proceedings: Visayas Regional Workshop in Developing the NBF for the Philippines, 12-13 January 2004.

6. Proceedings: Experts' Group Workshop in Developing the NBF for the Philippines, 08 October 2003.

7. Minutes of Meetings: National Coordinating Committee (NCC) Meetings 1 to 11, period 2003-2004.

In New Zealand:

8. The Biosecurity Strategy for New Zealand, August 2003.

9. Cabinet Papers: Biosecurity Strategy for New Zealand – Overview and Cross cutting Issues, 2003.

10. Memorandum of Understanding on Biosecurity Activities between MAF and DOC, MFish and MOH, June 2005.

11. ERMA Statement of Intent (SOI) 2004/2005

12. MAF SOI 2004/2005

13. MAF Annual Report 2003/2004

14. Proceedings 2nd New Zealand Biosecurity Summit, November 2004.

General:

15. UNEP-GEF Project on Development of National Biosafety Frameworks, PHASE 3 Toolkit Module Part (i) – Developing the Regulatory Regime, 2004.

16. Development of a Regional Risk Management Framework for APEC Economies for Use in the Control and Prevention of Introduced Marine Pests, 2001.

17. Towards a Food Secure Asia and Pacific: Regional Strategic Framework for Asia and the Pacific, Second Edition, 2004.

18. Setting a Research Agenda on Agricultural Biotechnology and Biosafety in Asia, 2005.

APPENDIX D

LIST OF OFFICES VISITED

In the Philippines:

1. Department of Science and Technology, Taguig, Metro Manila
2. Department of Agriculture, Diliman, Quezon City
3. Bureau of Agricultural Research (BAR), Visayas Ave., Quezon City
4. Department of Environment and Natural Resources – Protected Area and Wildlife Bureau, Quezon City
5. University of the Philippines - Los Baños, Laguna
6. International Rice Research Institute, Los Baños, Laguna

In New Zealand:

7. Ministry of Agriculture and Forestry, The Terrace, Wellington
8. Biosecurity Strategy Unit, The Terrace, Wellington
9. Environmental Risk Management Authority, Customhouse Quay, Wellington
10. Environment Canterbury, Christchurch.
11. University of Canterbury, Christchurch
12. Lincoln University, Lincoln.